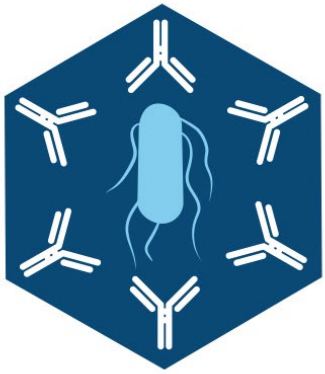
Protection **A**gainst **i**nvasive **N**on-**T**yphoidal **S**almonella Study



PAiNTS

Participant Information Sheet

We would like to invite you to take part in this new research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you.

Please take the time to read this Participant Information Sheet carefully. A member of the study team will then go through this information sheet with you and answer any questions you may have. Please talk to others, including your family and friends about the study if you wish. You do not have to take part in this study, and you can change your mind at any time.

Thank you for taking the time to consider taking part in this study.

Sponsor: Imperial College London
Sponsor reference: 24HH8722
IRAS Project ID: 344015
Research Ethics Committee: London - Riverside Research Ethics Committee
Research Ethics Committee Reference: 26/LO/0316
Study Funding: The Wellcome Trust (Reference 310277/Z/24/Z)

Chief Investigator: Dr Malick Gibani, Department of Infectious Disease, Imperial College London

Study Sites:

1. Imperial College Healthcare NHS Trust
    a. NIHR Imperial Clinical Research Facility, Imperial College Healthcare NHS Trust, Hammersmith Hospital Campus, Du Cane Road, London, W12 0HS
    b. Ward 15S and 15N, Charing Cross Hospital, Imperial College Healthcare NHS Trust Fulham Palace Road, London, W6 8RF

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Summary

About the study:

- You will be deliberately infected ("challenged") twice with *Salmonella Typhimurium*, a type of bacteria that usually causes diarrhoea and stomach upset (gastroenteritis).
- The two challenges will happen about 3–6 months apart.

Before joining:

- You will have screening tests to check it is safe for you to take part. These include: medical history, physical examination, blood and urine tests, an abdominal ultrasound, and a heart check (ECG).
- For some tests and procedures, you will need to fast (only drink water):
    - 6 hours before your ultrasound scan.
    - 1½ hours before each challenge.

How the challenge works:

- Under close medical supervision, you will swallow a small drink containing a measured amount of live *Salmonella*.

Hospital stays:

- You will stay in a single en-suite hospital room for two periods of 7 days (one for each challenge).
- You may be able to go home earlier if you start antibiotic treatment and symptoms have cleared up.
- Each day during the hospital stay we will collect blood and stool (poo) samples.
- If you still have significant symptoms or could pass on the infection, your stay may need to be extended.
- Visitors (one at a time) may be allowed, and you may be able to leave the ward briefly, depending on your symptoms.
- You can bring small personal items including phones, laptops, books or tablets to keep in touch, study, or relax.

After leaving hospital:

- You will have a short daily phone call with a study doctor for 6 days.
- You will attend at least five follow-up clinic visits (around 30 minutes each) over 6 – 9 months (two after the first challenge, three after the second challenge).
- You will also be asked to record your symptoms and diet in an electronic diary.

Possible symptoms:

- Most people develop symptoms of *Salmonella* infection such as diarrhoea, stomach ache, fever, headache, nausea, vomiting, tiredness, muscle or joint pain, and loss of appetite.
- These usually last a couple of days but may occasionally last longer.
- Serious illness is very rare in young, healthy people.

Treatment:

- You will be given antibiotics if your symptoms are severe enough, or if the infection has not cleared within 1 month of the second challenge.

Other important points:

- You will be reimbursed up to **£4,150** for your time and expenses if you attend all visits.
- You will receive emergency contact details for the study team.
- You will need to inform your household and close contacts if you take part.
- Female participants must use effective contraception (including barrier methods while on antibiotics) until cleared of infection.
- The study is funded by the **Wellcome Trust**.

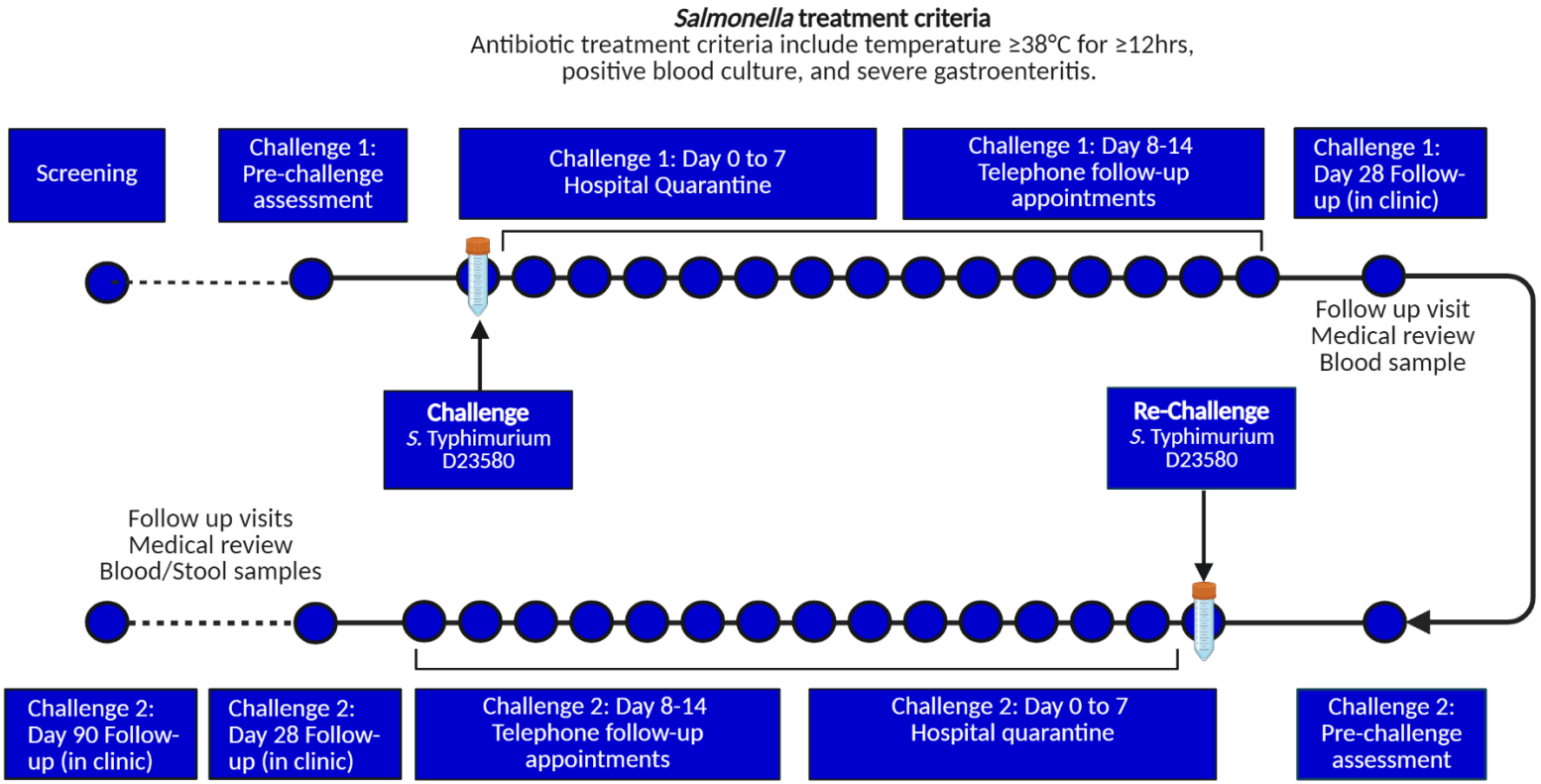


Figure 1- Study summary. The study will last 6-9 months, with the second challenge taking place between 3 to 6 months after the first.

BACKGROUND TO THE STUDY

Why have I been invited?

You are being invited to take part in a research study. Before you decide, it is important that you understand:

- why the research is being done
- what the study will involve
- what the possible benefits and risks are

We also need to check that you are healthy and at very low risk of becoming seriously unwell from the infection.

Please take the time to read this information carefully. You may wish to discuss it with friends, family, or others before making your decision. A member of the study team will go through this information with you, and you will have the chance to ask questions at any time.

Do I have to take part?

No. Taking part in this study is completely voluntary.

If you do choose to take part, you will be given a copy of this information sheet to keep and asked to sign a consent form. You are free to change your mind and withdraw from the study at any time, without giving a reason. This will not affect the medical care you normally receive.

If you withdraw, you will still be reimbursed for any time you have already spent in the study.

What are you studying?

We are studying a family of bacteria called *Salmonella*. There are more than 2,000 different types, each slightly different.

The type we are focusing on is called *Salmonella* Typhimurium. This is part of a group known as **non-typhoidal** Salmonella (NTS for short).

What illness does Salmonella (NTS) cause?

In most people, *Salmonella* (NTS) causes a gut infection called gastroenteritis. Common symptoms include diarrhoea, stomach-ache, and fever. These usually get better after a few days.

In some vulnerable people, the infection can be more serious. It can spread into the blood or other parts of the body, causing what is called “invasive NTS” (iNTS). This mainly affects people with weakened immune systems (for example, those with advanced HIV infection), very young children, older adults, or people with certain conditions such as malaria or sickle cell disease. This severe form (iNTS) is much more common in sub-Saharan Africa than in the UK.

How is it spread?

NTS is usually caught from contaminated food or water. It can also be passed from person to person if good hygiene, such as regular handwashing, is not followed.

Why are we studying Salmonella?

Invasive Salmonella (iNTS) is a serious health problem worldwide, especially in sub-Saharan Africa, where it affects more than half a million people each year. It mainly causes severe illness in young children who are malnourished or already unwell with conditions such as malaria, sickle cell disease, or HIV.

We are interested in finding ways to prevent iNTS, especially through vaccines.
Our group is studying NTS to help develop a safe and reliable way of testing future vaccines. We plan to do this using a type of study called a "human challenge study".

What is a human challenge study?

A human challenge study is a carefully managed medical research study, during which participants are intentionally given an infection in a safe way with healthcare support. These studies are done to understand diseases and find new ways to prevent and treat them.

You can read more about human challenge studies here https://www.hic-vac.org/public-information/human-infection-studies.

Why are you using a human challenge model for *Salmonella* (NTS) infection?

We know that these types of studies have been extremely useful in developing new vaccines for similar gut infections, like typhoid fever or cholera. In the future we plan to use a human challenge model to test new *Salmonella* vaccines. Having *Salmonella* vaccines that protect against severe disease could help save thousands of lives each year, especially of children living in sub-Saharan Africa where the disease is widespread.

What is the purpose of this study?

Our team set up the world's first human challenge model for *Salmonella* (NTS) infection, called CHANTS (https://www.imperial.ac.uk/infectious-disease/research/human-challenge/chants/). We found it is safe, and we know the symptoms that people usually experience. We also know what dose of bacteria to give people. Before we use the human challenge model to test vaccines, we want to better understand how our immune system reacts to the bacteria and protects us from future exposure.

What does the study involve?

You will take part in two "challenges" with *Salmonella* (NTS), given about 3–6 months apart.

At each challenge visit, you will drink a measured dose of *Salmonella* Typhimurium. This is given under close medical supervision. The bacteria have been prepared in a secure laboratory to make sure the dose is safe and consistent. We will then monitor you closely for two weeks.
For the first week after each challenge, you will stay in a single hospital room. Most people are discharged after seven days, but you may be allowed home sooner if you have started treatment and it is safe for you to do so. If you still have diarrhoea after seven days, you may need to stay a little longer until your symptoms improve.

After you leave hospital, a study doctor will call you every day for one week to check your symptoms and temperature. If needed, we will arrange a clinic visit. You will also attend about five follow-up visits (around 30 minutes each) over the next 6–9 months.

You will be offered antibiotics if you develop certain symptoms (such as a persistent fever or bacteria in your blood), or if *Salmonella* is still found in your stool two weeks after the second challenge.

We will collect blood and stool (poo) samples at most visits. These samples will help us study how the immune system responds to *Salmonella*, how it may protect against future infection, and how it affects the normal bacteria living in our guts. This knowledge will support the development of new vaccines.

GENERAL INFORMATION ABOUT THE STUDY

How many people will take part?

We aim to enrol up to 50 participants in this study. The final number may depend on what we observe during the study.

How do you make sure the study is safe?

Our team has already run the world's first Salmonella challenge study (CHANTS), involving 50 volunteers. From this, we identified the right dose of bacteria to use safely.

At Imperial College London (the study Sponsor), we also have extensive experience running other human challenge studies, including for influenza (flu), COVID-19, and RSV (a virus that causes coughs and colds).

This study has been carefully reviewed by independent experts and by Imperial College London to make sure it is designed and run as safely as possible.

Who can take part?

We are looking for healthy adults aged 18–50. To join the study, you must:

- understand what the study involves
- be willing to follow the study rules
- be in good health, with no medical conditions that would put you at higher risk
- weigh more than 50kg
- not have taken part in other Salmonella challenge or vaccine studies

- not have a job/studies that involve clinical healthcare, clinical or social work with direct contact with young children or adults susceptible to infections
- not have a job in commercial food handling
- not live with young children (under 5 years old), older adults (over 70 years old), pregnant women, or adults susceptible to infections

How long will the study last?

Your participation will last about 6–9 months.

There are two main "busy" phases, each lasting about two weeks:

- after the first challenge (at the start of the study)
- after the second challenge (3–6 months later)

The study includes:

- a screening appointment
- two pre-challenge assessments
- two 7-day hospital stays, which may be shorter or longer depending on your symptoms and whether you start antibiotics
- daily phone calls with a study doctor in the week after discharge following both hospital stays
- 2 follow-up clinic visits after the first challenge, and 3 follow-up clinic visits after the second challenge.

In total, you will have **8 short clinic visits** (Screening, two pre-challenge assessments, 5 follow-up appointments), **12 short telephone follow-up calls**, and **2 inpatient stays of approximately 7 days each** (14 inpatient days). The total number of days where you have a scheduled interaction is approximately 22. You may be asked to attend extra visits if needed for your safety.

How long will each visit last?

The screening visit lasts about 60 minutes. Most other visits last about 30 minutes. The hospital stays last around 7 days each, including overnight stays.

What will happen at the visits?

At most visits you will:

- speak to a study doctor or nurse about your health and any medicines you take
- have simple health checks such as blood pressure and pulse rate
- give a blood sample
- provide a stool (poo) sample

For stool samples you will sometimes be asked to collect them at home within 24 hours of your appointment. They should be kept in your fridge until you bring them in. We will give you a full kit (including gloves and a paper toilet insert) and advice on how to collect, store, and transport samples safely.

What are the main risks of taking part?

The possible risks include:

- developing a gut infection (gastroenteritis) with symptoms such as diarrhoea, stomach pain, fever, or vomiting.
- developing a more serious infection outside the gut, such as a blood infection (this is uncommon).
- side effects from antibiotics (for example, stomach upset, diarrhoea, or rash).
- rare complications after infection, such as:
    - irritable bowel syndrome (long-term bowel symptoms)
    - carrying *Salmonella* in your gut for a longer time
    - reactive arthritis (joint pain or swelling after infection)
- passing the infection to close contacts if strict hygiene advice is not followed.

You can find a full description of these risks, and how likely they are described later on in the booklet (section **What are the risks of taking part in the study?**). Please read this section carefully before deciding whether to take part.
At your screening visit, a study doctor will go through these risks with you and answer any questions.

What will happen to me if I take part?

In this section we will explain what taking part in the study involves, from first registering your interest, through to finishing the study.

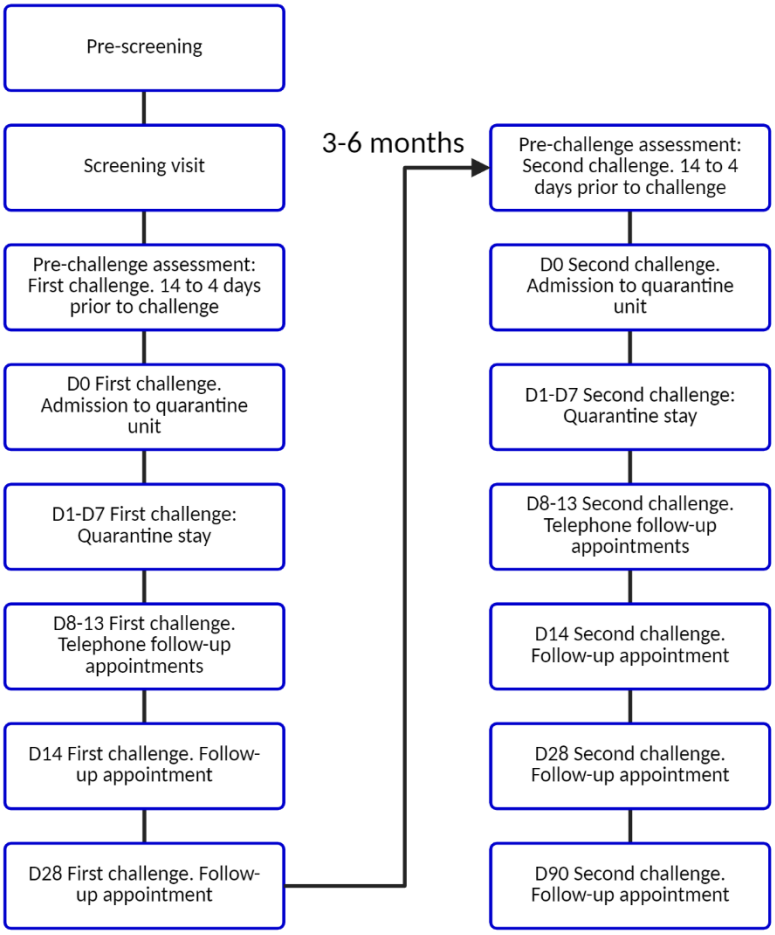


Figure 2 – Study schedule showing the flow of visits over the 6-9 month period. There might be additional unscheduled visits (not shown).

Pre-screening

The first step is to register your interest. You can do this by emailing the study team (paints@imperial.ac.uk) or by visiting our website.
You will be asked to:

- complete an online questionnaire about your health
- give permission for us to contact your GP for a summary of your medical history

If your questionnaire and GP information suggest you may be eligible, we will contact you by phone or email to explain the study in more detail and ask you some further questions. If you still appear suitable, we will invite you for a screening visit at the clinic.

What happens at the screening visit?

The screening visit is your chance to:

- learn more about the study
- ask questions
- take a short quiz about the study

- decide if you would like to take part

A study doctor will go through the study with you. If you wish to continue, you will be asked to sign an e-consent form before we carry out any checks.

Screening assessments

We carry out detailed checks to make sure it is safe for you to join the study. These include:

- medical history and lifestyle questions (e.g. who you live with, medicines you take)
- a physical examination (including heart, lungs, abdomen, blood pressure)
- blood tests (blood counts, kidney and liver function, blood clotting, infection checks)
- tests for hepatitis B, hepatitis C, and HIV
- ECG (heart tracing)
- urine test for kidney health or infection
- pregnancy test (for women)
- an abdominal ultrasound scan to check for gallstones (done at Charing Cross Hospital; you will need to fast (not eat food) for 6 hours beforehand)
- a short mental health questionnaire.

A full list of the tests is provided in the Appendix.

As part of the screening process for the study, we would need to test you for Hepatitis (B and C) and HIV. The hospital is required to report any new confirmed cases of Hepatitis to the UK Health Security Agency, as well as referral to an infectious disease clinician for management. With your agreement, in the case of a positive HIV test, we would inform your GP and the local HIV team, who will follow appropriate national reporting and management.

During screening, you will also be asked to provide your passport as identification and National Insurance (NI) number. Your NI number is entered into a secure national system called the Trial Over-volunteering Prevention Service (TOPS), which makes sure people do not join too many clinical trials at once. You cannot take part if you do not agree to this. Your passport and NI number will be kept confidential; please see "KEEPING YOUR DATA SAFE" for how we protect your privacy.

Other important points

- Attending a screening visit does not guarantee that you can take part. You may not be eligible, or the study may already be full.
- You will be reimbursed for attending the screening visit.
- Coming to screening does not commit you to joining. Even if you sign the consent form, you can change your mind at any time before drinking the challenge bacteria.

What will happen at screening?

1. Informed Consent
We will discuss the study with you in detail. If you are happy, we will ask you to sign a consent form

2. Quiz
We will ask you to take a quiz to check your understanding of the study

3. Medical History
We will ask you questions about your health and background

4. Medical Examination
We will check your temperature, blood pressure, heart rate and complete a medical examination

5. Blood Tests
We will do some blood tests to check your general health

6. Urine sample
We will ask you to provide a urine sample to check for kidney health and pregnancy in women

7. Questionnaire
We will ask you to complete a questionnaire to assess for anxiety and depression

8. Letter to GP
We will contact your GP to inform them you are taking part

9. Ultrasound scan
We will arrange an ultrasound scan of your abdomen to check you are eligible to take part. (NB This may happen a few days after the screening visit).

10. Eligibility assessment
Once we have all your results, we will contact you to let you know if you are eligible to take part

Figure 3 - Screening assessments that happen during the screening appointment.

What happens after the screening visit?

After screening, some people may decide not to continue, or the results may show it is not safe for them to take part. If this happens, we will contact you to explain why. If any test results need follow-up, we will also write to your GP. You will still be reimbursed for your time.
If your screening results are satisfactory, you will be invited to a pre-challenge assessment.

What happens at the pre-challenge assessment?

This visit takes place 4–14 days before your first challenge. It is the start of your formal enrolment.
At this visit we will:

- check for any changes in your health since screening
- carry out a brief medical examination
- collect blood and stool (poo) samples
- give you an electronic diary to record your temperature, stools, symptoms, and meals before and after each challenge

We will also confirm the date and time of your first challenge, which will be at either Hammersmith Hospital or Charing Cross Hospital.

What happens at the challenge visit?

The challenge visit is the start of the main study period.
At this visit we will:

- admit you to a dedicated hospital facility
- confirm you are happy to continue and ask if there are any health changes
- take a blood test (and a urine pregnancy test for women)
- ask you to fast for 90 minutes before the challenge

You will first drink a small amount of liquid to reduce stomach acid (to make sure the bacteria are not destroyed). Then you will drink a clear, tasteless liquid containing the *Salmonella* bacteria (about the size of two tablespoons). Afterwards, you will fast for another 90 minutes.

We will then admit you to your room, where you will be checked on regularly by the study team. We will collect a blood sample at approximately 12 hours after the challenge. We will check that you have filled in a diary reporting your symptoms, your temperature, and your diet and help as needed. We will ask you to carry on filling out your diary twice a day for the following two weeks after both challenges.

Do I need to prepare in any way for the challenge?

We will ask you to bring 2 stool (poo) samples on the morning of the challenge[1]. **Please also remember you will need to fast (not eat) for 90 minutes before and after drinking the challenge dose.**

[1] **This needs to be collected within 24 hours of the appointment and can be stored in a fridge after collection. We will provide you with the necessary kit to collect the sample and pots/bags to store it.**

What happens after the challenge? (Day 0 to Day 7 –stay in hospital)

You will be admitted to a quarantine unit in hospital for seven days and will be reviewed regularly throughout the day, every day. You might be discharged early if you have started antibiotics (see section Will I be treated with antibiotics?) and it is safe for you to go home. If you are discharged early, we would need you to come in for an extra visit on Day 7 (the day you were scheduled for discharge).

After the challenge you may or may not develop symptoms of *Salmonella* (NTS) infection. Around 70% of people develop clinical symptoms after challenge.

In the morning, we will first check that you are still willing to participate in the study. We would then review your symptoms, measure your temperature, pulse and blood pressure. After this, we will take a blood sample every day. This blood sample will be tested for the *Salmonella* (NTS) bacteria and used to study your body's immune response to the infection. If you agree, blood tests will also be taken for genetic analysis to see whether a particular genetic makeup can protect against infection and affect your response to the challenge (this is an optional part of the study).

Throughout the day, we will ask you to record every time you have a bowel movement. The study staff will help you to fill out your online diary using a chart (called a stool chart), that details how many times you have had a bowel movement, and whether you have had diarrhoea.

Over the course of each day, a member of the study team will come to visit you at regular intervals to check if there is anything you need and to check your temperature, pulse, blood pressure and your stool chart. We will ask everyone to update the study team if they develop any new or changing symptoms, so that we can offer you the best treatment.

During this time, it is very important that you do not take paracetamol, ibuprofen or any other medication that may lower your temperature unless instructed to do so by the study team, as this will interfere with the diagnosis of *Salmonella* (NTS) infection.

Re-challenge

3-6 months after the first challenge, we will repeat the challenge for a second time. The pattern and what will happen during these appointments is exactly the same. We will ask to see you 4-14 days before the re-challenge to make sure nothing has changed and you are still fit and well (the pre-challenge assessment).

Then we will admit you back to the dedicated facilities, check you are happy to proceed with the re-challenge, and give you the same two drinks (a stomach acid neutralising drink followed by the *Salmonella* NTS bacteria at the same dose as before). You will stay in the hospital unit for a further seven days so we can observe you. We will perform the same tests and ask that you fill out your online diaries again.

Unfortunately, you won't be eligible to take part in the re-challenge part of the study if we can still detect *Salmonella* bacteria in your stool (poo) at 6 months.

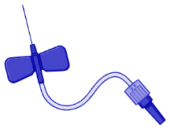
If this occurs, you won't be able to continue your participation in the study, and we will pay you for taking part in the first challenge only.

Instead, we will treat you with antibiotics and carry on monitoring you to ensure the infection clears up, liaising with your GP for longer term follow-up if necessary.

- **What happens after the first and second challenges? (Day 0 to Day 7 – stay in hospital)**

Medical Review
We will ask you questions about your health and how you are feeling

Examination
We will check your temperature, blood pressure, heart rate and take other measurements



Blood Test
We will take a blood test each day to check your health and to test for *Salmonella* infection

Stool sample
We will ask you to collect a stool (poo) sample when you have any bowel motions to test for *Salmonella* infection

Other samples
On some days we will collect other samples, like saliva

Online Diary
We will ask you to record any symptoms and food intake using an online diary

Stool chart
We will ask you to record when you have any bowel movements

Monitoring for treatment
We will monitor you closely to see if we need to start treatment

Figure 4 – The tests carried out and things we ask you to do during the inpatient stay.

Why do I need to stay in hospital, and what will it be like?

Everyone taking part will stay in hospital for about seven days after each challenge. This is so we can:

- monitor your health closely
- give you treatment (like antibiotics) quickly if needed
- reduce the risk of passing the infection to others

You will have your own en-suite room with TV and Wi-Fi. You can bring personal items such as a phone, laptop, or games console, and small exercise equipment (like a yoga mat). We will provide cleaning supplies for personal items before you leave.

Visitors

Visitors may be allowed one at a time if you have not had diarrhoea for 48 hours and are not considered infectious. Any visitors must follow strict hygiene rules.

Mixing with other volunteers

You will not be able to mix with other participants during your stay.

Food

Meals will be provided, and we can cater for vegetarian, vegan, or other dietary needs. You can also bring snacks or order food from outside the hospital. We will ask you to record what you eat in your study diary.

After the hospital stay

Most people will leave hospital on day seven, but you may be asked to stay longer if you still have symptoms. After discharge:

- a study doctor will call you every day until day 13
- if you leave early, you will return for a visit on day 7

You will also have follow-up clinic visits on:

- Day 14 and Day 28 after the first challenge
- Day 14, Day 28, and Day 90 after the second challenge

These visits last about 30 minutes and include a health check, blood test, and stool (poo) sample. We will use these samples to check for *Salmonella* and study your immune response. You must remain contactable by phone or email until we confirm that *Salmonella* has fully cleared after the second challenge.

If you develop severe symptoms after leaving hospital, we may ask you to return to hospital for further care.

What happens if I get Salmonella (NTS) symptoms?

Symptoms can begin any time after the challenge, usually within 12–48 hours, but sometimes earlier or later. Most people's symptoms last 3–7 days.
In healthy young adults, infection is usually mild and gets better on its own. Common symptoms include:

- diarrhoea
- stomach pain
- fever
- headache
- nausea or vomiting
- tiredness
- muscle or joint aches
- loss of appetite

If your symptoms are more severe, we will start antibiotics. This will help shorten the illness. We can also give medicines to lower your temperature, treat nausea, or replace lost fluids if needed.

Could I get severe symptoms?

This is very unlikely in healthy people. If you did become unexpectedly unwell, you might be moved to a hospital ward for closer monitoring until you recover. There is a very small risk of more serious illness or complications, which we describe in more detail later in this booklet.

Can I pass Salmonella (NTS) to others?

The risk is very low if you follow the hygiene rules we give you.
We ask you to let people you live with (such as a partner or housemates) know you are taking part and we can provide them with an information sheet.

Public health notification

By law, all cases of *Salmonella* must be reported to local public health authorities. We will do this on your behalf. We will share only basic details: your name, address, phone number, and the date and time of your challenge. We will also inform them when you start antibiotics and when tests confirm you are clear of infection.

If you are contacted by public health staff, please ask them to contact the study team directly on **07894 986332** or **paints@imperial.ac.uk**.

Will I be treated with antibiotics?

Not everyone will need antibiotics. You will be given antibiotics if:

- you have a persistent high temperature (38°C or higher for 12 hours or more)
- *Salmonella* is found in your blood
- you have significant diarrhoea or other strong symptoms

- the study doctors think it is needed for your safety

If you have no symptoms and repeated negative tests, we may not recommend antibiotics as Salmonella is cleared spontaneously in most people without them, and antibiotics can prolong the risk of shedding (passing *Salmonella* in stool). However, you can still ask for treatment if you would prefer.

If bacteria are still present after treatment, you may be offered a short course of a second antibiotic.

Which antibiotics will I be given?

The main antibiotics we use are called Azithromycin (a tablet, usually once daily).

It is widely used and effective against *Salmonella*. Most courses last 5 days.
In some cases, we may use other antibiotics called ciprofloxacin (a tablet, twice daily) or ceftriaxone, which is given in hospital. If *Salmonella* is found in your blood, treatment will last longer (10–14 days).

What are the possible side effects?
Most people do not have side effects. Some may experience:

- diarrhoea
- stomach upset

More details about antibiotic side effects are provided later in this booklet.

Will I be followed up afterwards?

Yes. After the second challenge you will have follow-up visits at 1 month and 3 months.
You can also contact the study team at any time between visits. If needed, we can arrange extra appointments. We will confirm or update appointments with you by phone or email.

If, at your final planned visit after the second challenge, your stool sample still shows *Salmonella*, we may offer you extra follow-up visits. These are called "unscheduled visits" because they are not part of the standard visit schedule. At these visits, you would provide further stool samples so that we can check when the Salmonella has cleared. We would usually not give antibiotics in this situation, as most people clear the infection naturally, but we will give you clear advice on hygiene to reduce any risk to others. These extra visits are optional, and you would be compensated for your time and travel. We would continue this follow-up until we have at least two stool samples in a row that are negative for Salmonella.

What samples will you collect?

- At screening: blood and urine (to check your general health)
- During the study: blood and stool (poo) samples at most visits, and sometimes saliva

These samples help us monitor your health and understand your immune response. Some are for research only, and we cannot give you those results, because they are done to look at overall

patterns and carried out in labs that aren't certified to return results to participants. This means the results might not be accurate or complete enough to interpret for one person. However, we can share the results of your routine tests if you would like.

Over the whole study, we will take about 976 ml (1 litre, or about two pints) excluding any extra visits. For comparison, blood donors give about that amount in a year. To protect your health, you should not donate blood for a whole year after joining the study.

What happens to my samples?

Your samples will be analysed in NHS Hospital Trust and Imperial College London research laboratories. Some may also be sent to our partners, including researchers outside the UK and EU. These samples will be anonymised so you cannot be identified. More details on privacy and data storage are at the end of this booklet.

Emergency contact

We will ask you to give us the name and phone number of someone who lives with or near you, who can be contacted if we cannot reach you. If you miss a visit and we cannot contact you, we may call this person or, if necessary, check your home address until we confirm you are free from Salmonella.

In the very unlikely event that we are unable to reach you or your chosen contact after several attempts, and we are concerned about your wellbeing (particularly during the daily follow up period while you are at home), we may ask the police to carry out a wellbeing check. This would only be to make sure that you are safe and well. It is a routine and supportive step, and not a cause for alarm. Our only intention would be to ensure you are okay and to offer help if needed.

Future research (optional)

We may ask to store some of your blood (including DNA), saliva (to look for antibodies), and stool samples in a biobank for future research. These will not contain any details that can identify you. You can say no to this and still take part in the study, we will ensure your samples are destroyed at the end of the study. If you agree, you will sign an optional section on the consent form.

Will you be looking at my genes?

Some of your blood samples may be used for genetic research. Genes are the "instructions" in your body that influence how you respond to infections and medicines.

We will study genes linked to protection against infection. This may include:

- looking at which genes switch on or off during *Salmonella* infection
- checking for inherited (or acquired) differences in DNA that affect the risk of symptoms

These tests are for research only. We will not be looking at all your genes. They will not be used to diagnose health problems, and neither you nor the study doctors will receive the results.

Taking part in genetic testing is optional. You can still join the study if you say no. You can also change your mind later but results already analysed cannot be withdrawn. If you agree, you will sign an optional section on the consent form.

What if any of my test results were abnormal?

If any of your health tests show an unexpected problem, we will discuss this with you and inform your GP (with your consent). For example, we may find high blood pressure.

Please note: new diagnoses may affect future applications for life insurance, health insurance, or travel cover.

Is there any risk if I were to get pregnant?

Yes. Salmonella infection can be dangerous during pregnancy for both mother and baby. Women will be asked to use effective contraception until the infection has fully cleared (including extra precautions while taking antibiotics). Pregnancy tests will be done at screening and before both challenges. If you are pregnant at any of these stages, you will not be able to take any further part in the study.

Protecting Others (stopping infection spreading)

As this is an infection study, protecting your family, friends, and the wider community from possible transmission is paramount.

Before you are enrolled, we must exclude people whose work carries a high risk of spreading infection. This includes anyone who:

- **Works in food handling or catering**, especially with unwrapped food that is not reheated.
- **Works in healthcare or social care** (including students) with direct contact with patients or service users.

To prevent the possibility of spreading the study infection after you leave hospital, you must avoid close contact (e.g., sharing towels, preparing food for them, or intimate contact) with individuals who are most vulnerable. This includes:

- **Young children** (aged under 5)
- **Pregnant women**
- **Individuals with a weakened immune system** (e.g., those undergoing cancer treatment, organ transplant recipients, or people with certain long-term illnesses).

We must exclude people who live with the most vulnerable people because of the risk to them. If you are unsure whether a person you know is considered vulnerable, please discuss this with the study team.

What are the risks of taking part in the study?

Because this study involves deliberately giving you *Salmonella*, there are some risks. We have designed the study to keep these risks as low as possible, but they are not zero.

Most people taking part are expected to develop symptoms of *Salmonella* infection, although some may remain well.

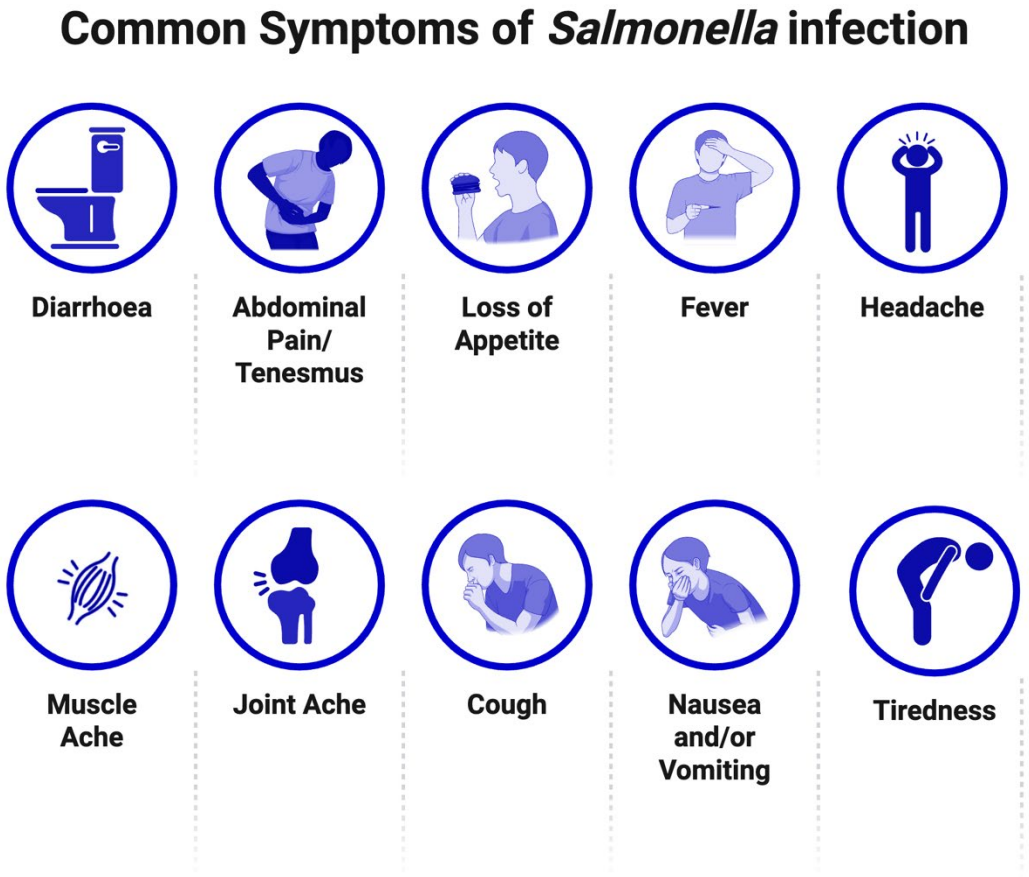


Figure 5 – Common symptoms of Salmonella infection. As part of this controlled human infection study, some participants are expected to develop symptoms of Salmonella infection such as those shown above. In previous studies, these symptoms have typically been mild to moderate, lasting for around 24–48 hours. Most symptoms occur while participants are in hospital, where they are closely monitored by the study team and provided with appropriate treatment and supportive care as needed.

While most people experience only the short-term symptoms shown above, a small number may experience other effects or complications, which are uncommon and explained in the next section.

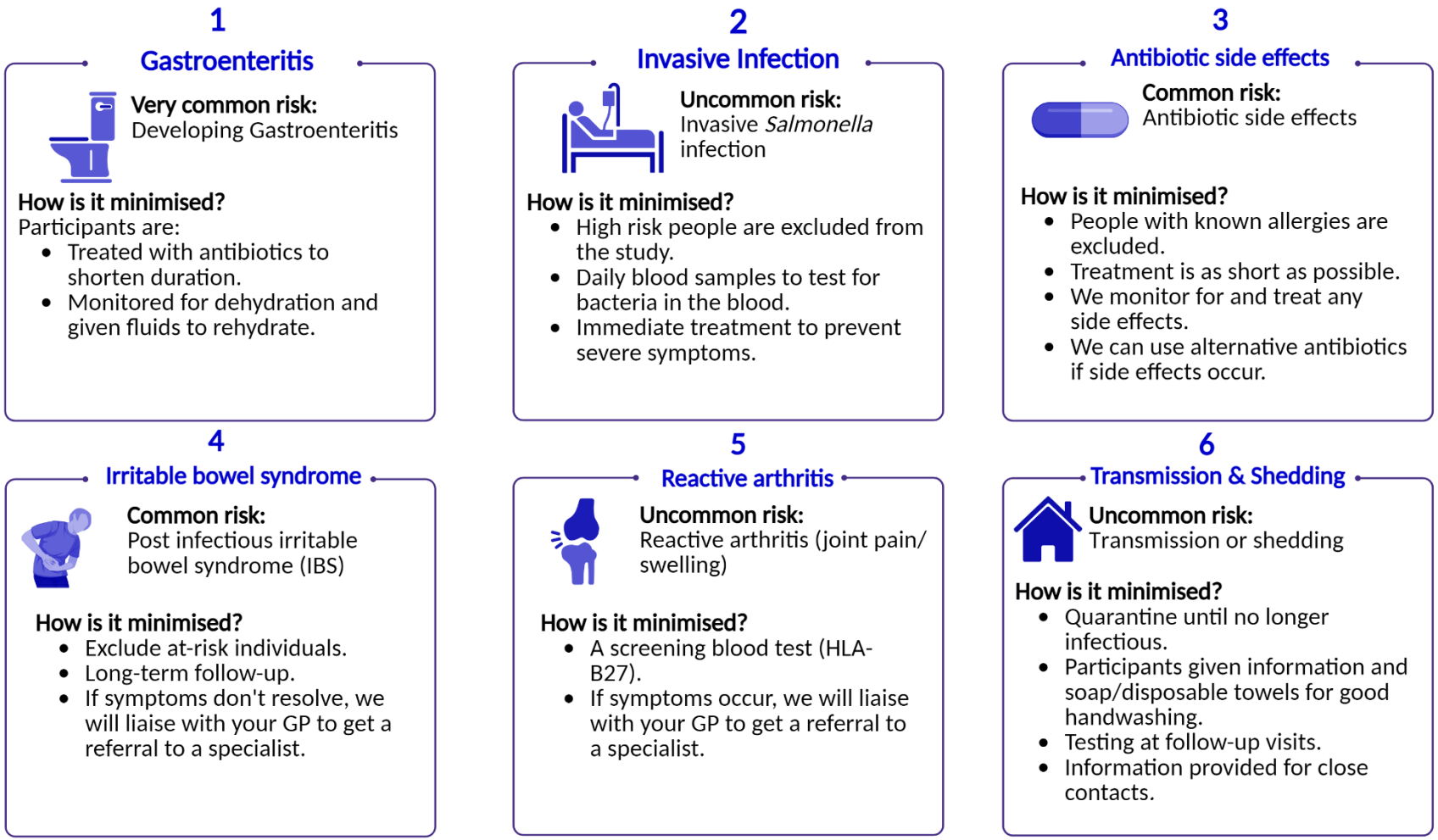


Figure 6 - Possible risks and how we minimise them.

What are the main risks of taking part?

We expect most volunteers to develop some symptoms of *Salmonella* infection. These are usually mild to moderate and get better on their own or with treatment. Below we explain the possible risks, how common they are, and what we will do to reduce them.

1. Gastroenteritis (very common)

The most likely risk is gut infection, with symptoms such as:

- diarrhoea (sometimes with blood)
- stomach pain
- fever
- headache, tiredness, or loss of appetite
- nausea or vomiting
- muscle or joint aches

Symptoms usually begin within 12 to 48 hours. They sometimes start earlier or later. Most last two to three days.
Main concern: dehydration.

How we minimise this risk:

- close daily monitoring in hospital
- fluids and guidance on how much to drink
- IV (intravenous, via your veins) fluids if needed
- antibiotics if symptoms become more intense

We will also support participants by providing advice on what to eat (and what to avoid) post-gastroenteritis, and suggestions on foods that support the gut microbiome during recovery.

2. Invasive Salmonella infection (uncommon)

In rare cases, the bacteria can spread into the blood and cause a more serious illness. If untreated, this can lead to sepsis, meningitis, or infections in bones, joints, or blood vessels.

How we minimise this risk:

- daily blood tests while you are in hospital
- early antibiotics if bacteria are found in your blood
- close monitoring after you leave hospital, with immediate review if you develop a fever

3. Irritable Bowel Syndrome (IBS) after infection (common)

Some people may develop longer-term bowel symptoms such as cramps, wind, or changes in stool frequency. This usually improves with time but can last for weeks or months.
How we minimise this risk:

- exclude anyone with pre-existing IBS
- follow you closely for up to 9 months
- contact your GP (with your consent) if symptoms persist

4. Reactive arthritis (uncommon)

A small number of people may develop joint pain or swelling 1–4 weeks after infection. Symptoms usually resolve within 6–12 months, although rarely they may last longer.

How we minimise this risk:

- test you for a genetic marker (HLA-B27) before joining the study
- refer you to your GP and a specialist if symptoms occur

5. Antibiotic side effects (common)

Antibiotics are usually well tolerated, but possible side effects include:

- diarrhoea, nausea, vomiting, or loss of appetite
- headache, tiredness, dizziness, or thrush
- changes in taste

Rare side effects include rash, mood changes, or liver or kidney problems,. Very rarely, antibiotics can trigger allergic reactions, including severe reactions (anaphylaxis).

Antibiotics may also:

- reduce the effectiveness of the contraceptive pill (we recommend using condoms as well)
- interact with antacids and iron supplements
- increase the chance of carrying drug-resistant bacteria in the future

In some situations, such as if *Salmonella* is found in your bloodstream (uncommon), the study doctor may recommend treatment with an antibiotic called ciprofloxacin (a type of "fluoroquinolone" antibiotic). Ciprofloxacin is an established treatment for this kind of infection, but the UK medicines regulator (MHRA) has highlighted some important safety issues that you should be aware of. Rarely, ciprofloxacin can cause serious side effects that may be long-lasting. These can affect:

- tendons, muscles and joints (for example, pain, swelling, or rupture of a tendon – often around the ankle/heel)
- nerves (for example, pain, burning, tingling, numbness or weakness in the arms or legs)
- the brain and mental health (for example, confusion, agitation, low mood, or sleep problems)

Because of this, ciprofloxacin will not be used routinely in this study. It will only be offered if the potential benefits clearly outweigh the risks, and after the study doctor has checked that you do not have important risk factors such as a previous serious reaction to this type of antibiotic, certain tendon problems, or particular heart or seizure conditions.

If you are given ciprofloxacin, you will receive written information about these risks and clear instructions to:

- stop the tablets immediately and contact the study team (or seek urgent medical advice) if you develop pain, swelling or weakness in a tendon or joint;

- stop the tablets and contact us if you notice symptoms such as burning, tingling, numbness, unusual pain in your arms or legs, or new/worsening mood, sleep or mental health symptoms.

How we minimise this risk:

- exclude anyone with known antibiotic allergies
- keep courses as short as possible
- switch or stop treatment if side effects develop
- perform regular blood tests to check for problems early
- advise avoiding iron tablets/antacids while on antibiotics
- provide 24/7 access to a study doctor for advice

6. Risk of transmission (uncommon) and shedding (common)

Salmonella (NTS) is usually caught from contaminated food. The chance of passing it to others is very low if you wash your hands well after using the toilet and before preparing food. Cooking food properly also kills the bacteria.

A small number of people (1%) can carry the bacteria for a year or more – this is called being a "chronic carrier". This almost always happens in people with gallstones, which is why we will scan your gallbladder before the study. If gallstones are found, you cannot take part.

How we minimise this risk

- People with close contacts at higher risk (young children, pregnant women, or those with weak immune systems) cannot take part.
- People working in food handling, health, or social care cannot take part.
- You will stay in hospital during the period you are most likely to be infectious (when you may have diarrhoea).
- After discharge, you will be given clear hygiene advice, plus antibacterial soap and paper towels.
- We can provide your close contacts with information, and, if requested, a stool test to check they are not infected.
- Two to four weeks after the second challenge, you will provide 3 stool samples at least 48 hours apart to confirm the infection has cleared.
- We would offer extra follow up visits at the end of the study to ensure the infection clears up.

Shedding after infection

- Most people clear *Salmonella* within a matter of weeks.
- Sometimes the bacteria can linger in the gut for weeks or months without causing symptoms ("convalescent shedding").
- Very rarely, bacteria remain for a year or more ("chronic carriage").

If you carry *Salmonella* without diarrhoea, you are unlikely to pass it on. However, until you provide samples to prove that you have cleared the infection we ask you to:

- wash your hands regularly
- avoid close contact with young children, pregnant women, and people with weak immune systems
- avoid food handling work
- continue effective contraception

Are there other risks of taking part?

- *Post-infectious complications:* Some people may develop delayed symptoms after infection, due to the immune system reacting abnormally. These can affect areas outside the gut (for example, joints).
- *Emotional wellbeing:* Staying in quarantine in hospital may feel stressful, lonely, or isolating. You will be able to make phone and video calls, and limited visitors (one at a time) may be allowed under strict hygiene rules.
- *Privacy and space:* Your room will be private but staff will check on you regularly.
- *Tests and procedures:* Some tests (such as HIV screening) may feel stressful.
- *Insurance and benefits:* You should check whether taking part could affect any insurance policies (like travel, health) or state benefits.
- *Work and career:* Long-lasting symptoms, while unlikely, could affect your work. Compensation arrangements are described later.
- *Blood tests:* These may cause mild pain or bruising. Rarely, people may feel faint.
- We will keep you updated if any new information arises that could affect your decision to stay in the study.

What are the advantages of taking part?

There is no direct health benefit to you. However, you will receive information about your general health from screening tests. More importantly, your participation will help improve understanding of *Salmonella* (NTS) and support the development of new vaccines.

Payment

You will be reimbursed up to **£4,150** if you complete the whole study, covering time, travel, and inconvenience.

You will be paid **£151.80** if you only take part in screening.

You will be paid **£2,127** if you only take part in the first challenge.

Breakdown of payments:

- Travel: **£16.30 per visit**
- Blood tests: **£10 each**
- Ultrasound scan: **£50**
- Providing clearance stool samples: **£10 each** (up to £60 for 6 samples)
- Time off work: based on London Living Wage **(£14.80/hour)**

If you need extra visits for safety follow-up (up to 10):

- Travel: **£16.30**
- Blood test: **£10**
- Time off work (1.5 hours at £14.80/hour): **£22.20**
- **Total per extra visit: £48.50**

Payments will be made by secure bank transfer. Your banking details will be stored confidentially by Imperial College London and only kept while you are actively in the study.

- **When and how will I be paid?**

Payments will be made after these visits:

- Screening
- Day 28 after the first challenge
- Day 28 after the second challenge
- 3 months after the second challenge

Payments are usually processed within **4–6 weeks**.

Reimbursement for "time off work" only covers the **seven days of hospital stay** after each challenge. We cannot cover any time off work after this period. If you withdraw or leave the study early, you will still be paid for the parts you have completed, based on the payment breakdown already described.

We will not deduct tax or National Insurance from your payment. It is your responsibility to check whether this affects your personal tax, benefits, or allowances. For more information, you can contact HM Revenue & Customs (HMRC) http://www.hmrc.gov.uk or call 0300 200 3300.

In certain situations, we may be required to inform the authorities about your payments if asked.

Medical photography and film

If you develop visible signs of *Salmonella* (NTS) infection, we may ask for your permission to take photographs or short films. These may be used for:

- clinical discussions
- scientific publications
- educational events (such as conferences)

This will only be done with your consent. Saying no will not affect your participation. If you agree, you can choose how the images are used. All images will be stored securely, with your identity protected. In rare cases, we may ask to take an identifiable image (for example, of your face), but this would only happen with your explicit permission.

What if I want to stop taking part?

You can withdraw from the study at any time, without giving a reason.

If you decide to leave after drinking the *Salmonella* (NTS) bacteria, you will need to take the course of antibiotics and provide stool samples. This is important for your safety, as untreated

infection can have serious consequences. We will also make sure you receive proper follow-up care through your GP or the local health protection team until you are clear of infection. Taking part in this study won't impact any future care you receive for other medical conditions.

Who can I contact during the study?

You will have 24-hour access to a study doctor throughout the trial. It is very important that you let us know straight away if you develop a fever or feel unwell at any time**.**

LEGAL INFORMATION
In this section we outline important legal information relating to the study.

What if I want to withdraw from the study?
You are free to withdraw from the study at any time you wish. If you decide to withdraw your consent and 'leave the study' during the hospital phase, you will be very strongly encouraged to remain in the hospital unit until you are no longer contagious. This is for both your safety and that of others whom you could infect as a contact. In this situation, we would continue to offer you all procedures considered important for safety purposes by the study team but would stop any research procedures. This would include:

- Regular vital sign checks (heart rate, blood pressure, temperature etc.)
- Medical review of any symptoms
- Safety blood tests (but not research ones)
- Antibiotic treatment

By remaining in the unit, it would allow close follow-up by the study medical team and for us to monitor your treatment. If you have to leave the hospital unit before you have been formally discharged, we will contact the local health protection team, who may wish to follow you up in the community.

If you decide to leave the unit early:

- You will be advised about hand-washing and other infection control measures
- You will need to be transported home in private transport
- With your agreement, you will be contacted daily by the study staff (i.e., study doctor or nurse) via phone call to check on your health and to remind you of any self-isolation requirements until the study doctors are satisfied that daily follow up can end.

If you withdraw from the study, any samples and data collected before your withdrawal will be used/stored unless you specifically request otherwise. If any of your anonymised data has been incorporated into the study, it will not be withdrawn or erased to comply with our legal obligations and to maintain the scientific integrity of the study.

What if something goes wrong?
You must tell the study staff immediately if you have any health problems during the study. You will be given an emergency contact card when you are discharged from hospital, which provides a 24-hour telephone service in case you need to contact us outside of office hours. If you need to see another doctor for health problems relating to the study, we will ask that doctor to provide

details that will help us follow up your care and investigate the possible reasons for these health problems.

If you are injured or experience symptoms worse than the mild short-term symptoms listed above, we will offer you the appropriate treatment. If you suffer any significant worsening in health or well-being caused directly by participation in the study, your medical care will be provided by the National Health Service (NHS).

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.
If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr Malick Gibani, m.gibani@imperial.ac.uk). The normal National Health Service mechanisms are also available to you (https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/). If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team (https://www.imperial.ac.uk/research-and-innovation/research-office/research-governance-and-integrity/).

Who is organising and funding the research?
This research is funded by the Wellcome Trust. The study is being sponsored by Imperial College London. The trial itself will be conducted at the Imperial Clinical Research Facility (located at Hammersmith Hospital) and Charing Cross Hospital, both Imperial College Healthcare NHS Trust sites.

Who has reviewed the study?
The study has been reviewed by the study sponsor (Imperial College London). It has been approved by an independent research ethics committee (London - Riverside Research Ethics Committee Reference 26/LO/0316) and has also been approved by the NHS (Research & Development approval).

Is there anything else I should know?
If you have private medical insurance, you are advised to contact your insurance company before participating in this trial. Imperial College London, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

In the event of a study participant experiencing a serious adverse event, permission may be sought from you to access medical records (e.g. discharge summaries or correspondence) from NHS services. In the unlikely event that you become very unwell, you will be admitted to the Infectious Diseases Ward or other suitable wards at the participating hospital. Your care at this point will be under the admitting Consultant and their team and NHS medical records will be used. The study team will seek permission from you to access these medical records as needed. By agreeing to take part in this study, you do not give up any legal rights to other treatments that maybe be available to you for an injury or illness caused by the study or study procedures.

Individual researchers do not receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research.

Has the clinical study been registered?
A description of this study will be available on a clinical trials database e.g., https://www.isrctn.com/. This will not include information that could identify you. At most, the website will include a summary of the results. You can access the results of the study by visiting either website and searching for the study details included in this participant information sheet approximately one year after the trial has ended. We will also contact you by email to share the study results with you if you consent.

KEEPING YOUR DATA SAFE

How will we use information about you?
Imperial College London is the sponsor for this study and will act as the Data Controller for this study. Being a Data Controller means that we are responsible for looking after your information and using it appropriately plus are responsible for explaining this to you. Imperial College London will keep your personal data for:

- A minimum of 10 years after the study has finished in relation to data subject consent forms.
- A minimum of 10 years after the study has completed in relation to primary research data.

The study data will then be fully anonymised and securely archived or destroyed.

The study is expected to finish in December 2028.

For more information / confirmation regarding the end date please contact the study team, see **'Where can I find out more about how your information is used?'** for contact information.

We will need to use information from you, your medical records and possibly your GP for this research project. This information will include:

- your full name
- address
- contact details
- date of birth
- sex at birth
- NHS number
- medical history
- banking details

People within Imperial and Trust study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact) details is accurate.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Imperial is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by:

- Following Data management plans that have been created and reviewed in line with Imperial's Information Governance Policy Framework. This covers the collection, movement, processing, and storage of the data.
- Storing data in a dedicated secure environment which underpins security measures.
- Storing data in ISO 27001 certified and/or Cyber Essentials accredited environments.
- Robust pseudonymsation (where your samples/data are labelled with your individual study code, but not your name or other identifiable details like date of birth) has been implemented to prevent identification.
- Implementing Access controls to ensure only key personnel can access the data.

Some of your information (e.g. your age, sex at birth and medical data collected during the study) will be sent to research partners based in countries in the European Economic Area or countries outside the European Economic Area. They must follow our rules about keeping your information safe. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

As a university we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

- Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.). Imperial College London relies on "scientific or historical research purposes or statistical purposes".

International Transfers

We may share data about you outside the UK for research related purposes to:

- Where necessary to share with a third-party organisation/collaborator who are involved in the study.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Other universities who are carrying out data analysis from the Study.
- Other universities or commercial companies performing laboratory assays and results analysis using samples collected during the study.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts which stipulates that personal data must maintain the same level of protection when outside the UK as it has within the UK. For further details visit the Information Commissioner's Office (ICO) website - www.ico.org.uk.
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website - Personal data breaches: a guide | ICO.

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.). Imperial College London agents, contractors, and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

- Your GP – To enrol into this study, you would be required to sign a form, documenting that you consent for us to contact your GP. This is to inform them that you would be entering the study, to ensure there are no medical reasons that would prevent you from taking part in this study, and to inform them of any test results that might need further investigation or a referral for on-going care.

  UK Health Security Agency and your local Health Protection Team - We would inform the local health protection unit of your name, address and date of birth after you were challenged with *Salmonella* (NTS). This is to ensure that there is independent oversight of the public health aspects of this trial.
- The following Research Collaborators / Partners in the study:
  - The University of Oxford – Collaborators based at the University of Oxford are providing statistical support to the study team and performing some laboratory analyses. Outcome data (including the results of laboratory tests and/or genetic testing and/or transcriptomic data) may be shared to aid the analysis.
  - GSK – Collaborators at the GSK Vaccines Institute for Global Health (GVGH) will be receiving samples and basic information about you (age, sex, and outcome of

challenge) to analyse. The samples will be pseudonymised using a code assigned to you and will not contain any genetic information.
- The University of Edinburgh – They are leading the overall program and we will share some of your data with them. It will be pseudonymised, so they will not be able to identify you.
- The University of Liverpool – Collaborators will be studying other bacteria living in your gut (the microbiome) to see how *Salmonella* infection affects them.
- Any research collaborator or partner who carries out genetic testing or analysis will be processing identifiable data. We will have robust agreements in place ensuring they comply with GDPR and our data protection schedules.

Potential use of study data for future research

When you agree to take part in a research study, the information or samples collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, be used against you or used to make decisions about you.

Commercialisation

Samples and/or data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You have the right to ask us to access, remove, change, or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your central NHS records, your hospital or your GP for the duration of the study. If you do not want this to happen, tell us and we will stop.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

If you lose capacity to consent during the study, all identifiable data and samples will be withdrawn. Data and samples that is not identifiable may be retained.

Where can I find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to the chief investigator m.gibani@imperial.ac.uk
- by going to our website pages [www.imperial.ac.uk/infectious-disease/research/human-challenge/paints]

Complaints

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to Malick Gibani (m.gibani@imperial.ac.uk) or by ringing us on 07894986332.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

What will happen to the results of the study?

The results of the study will be published via peer-reviewed scientific journals, conference presentations, and publications on website. If any results or publications are made publicly available during your participation in the trial, the study team will inform you where you can read these or provide you with a copy if you consent to being contacted. If any results or publications are made publicly available after you have completed the trial, information about these can be found on the www.imperial.ac.uk/infectious-disease/research/human-challenge/paints. You will not be identified in any report/publication.

Thank you for reading the information sheet!

Appendix

What tests will be performed at the screening visit?

This looks like a long list, but each test is quick and routine

- Full blood count
- Urea and electrolytes
- Liver function tests
- C-reactive protein
- Serum IgA
- Coeliac serology
- HLA-B27 screening
- Coagulation screen
- Haemoglobinopathy screen
- HIV 1&2 antibody
- Hepatitis B surface antigen
- Hepatitis C IgG
- Ultrasound of the biliary tract
- Ultrasound of the abdominal aorta.
- Malaria screen
- Urine pregnancy test
- HbA1c (test of blood sugar)
- ECG
- Resting heart rate, respiratory rate, blood pressure, oxygen saturations and oral temperature.
- Stool culture for *Salmonella* (performed after screening at Day-7 visit if enrolled).

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