Please print on headed trust paper

Centre Number: _____
Patient Study Identification Number: _____

Patient Information Sheet Asp-PSC

Full title: Asp-PSC: Effect of Aspirin on Reducing Cancer and Improving Outcomes in Primary Sclerosing Cholangitis

Introduction

You are invited to take part in a research study. This information sheet will explain why the research is being done and what it would involve for you. **Your study doctor and hospital team will go through the information sheet with you and answer any questions you have**. Please read the information carefully and talk to others about the study if you wish, including your General Practitioner (GP).

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask if anything is unclear, or if you need more information. Take as much time as you need to decide whether to take part. If you decide you want to take part, you will be asked to sign the consent form. You will be given a copy of this consent form. This is to ensure that you fully understand what is involved if you agree to take part.

Thank you for taking the time to read this information sheet.

1. What is the purpose of the study?

The study is looking at whether aspirin is safe and effective in reducing cancer and increasing survival, in people with both PSC (primary sclerosing cholangitis) and IBD (inflammatory bowel disease).

Some people with PSC develop liver failure and need a transplant, and some have an increased risk of developing cancer in the liver, bile ducts, gallbladder, or bowel.

Although an annual colonoscopy is performed to look for signs of bowel cancer, detecting the other cancers is currently more challenging. There is therefore a need to find medications that can effectively reduce and manage the risk of cancer and associated complications in people with PSC and IBD.

Aspirin is a common drug used to treat pain and reduce the risk of heart attack and stroke. Recent clinical trials and research suggest that taking aspirin regularly may reduce the risk of developing some cancers in the general population. This large United Kingdom (UK) wide study will be the first

to see if low dose aspirin is safe and effective in reducing the risk of cancer, as well as the need for liver transplantation, and in increasing overall survival, in people with both PSC and IBD.

2. Why have I been invited to take part?

You have been invited to take part because you have both PSC and IBD and your doctor thinks you may be suitable or you are part of the NIHR BioResource and have agreed to be invited to research studies that you may be eligible for.

Over 900 volunteers from approximately 60 hospitals across the UK will take part in Asp-PSC.

Do I have to take part?

No. It is up to you to decide whether to take part or not. If you prefer not to, you do not have to give a reason. If you do decide to take part, you will be asked to sign a consent form and given a copy to take away with you. You are free to withdraw at any time, without giving a reason. The usual care you get from your GP and hospital consultant **won't be affected, whether you decide to take part in the study or not.**

Your study doctor or the study sponsor (Imperial College London) may decide at any time to stop the study treatment, even though you may want to continue e.g., if you have unacceptable side effects.

3. What will happen to me if I can take part?

If you take part, you will be in the study for 5 years. After 5 years, we will collect some medical information about your health from your hospital, but you are not required to attend anymore visits.

You will be asked to attend your hospital for study visits and have certain tests and assessments that are explained later in this information sheet. You should consider how taking part will affect your work and family life and decide if you are able to commit to this.

Randomisation: what does this mean?

This study is 'randomised'. This means that a computer will allocate each person taking part to one of two treatments:

- Aspirin, which will be in tablet form. 645 people will receive aspirin and so you'll have a 2 in 3 (two thirds) chance of being allocated aspirin;

- A matched 'placebo' (dummy tablet), which will look identical to the aspirin. 323 people will receive the placebo and so you will have a 1 in 3 (one third) chance of being allocated the placebo.

Why is randomisation and a placebo being used?

A placebo tablet will look like aspirin but will not contain any medicine inside. It is an inactive

substance. You may receive the placebo. The study researchers compare the placebo group to the aspirin group to see if aspirin is really helping people with PSC and IBD.

A randomised placebo-controlled study is the best way of doing this and is used in many clinical trials. The 2 in 3 (two thirds) chance of receiving aspirin has been specifically chosen to allow the maximum possible number of people taking part to receive it.

Will I and my study doctor and hospital team know which treatment I receive?

No, you and your study doctor and hospital team will not know which treatment you will receive, i.e., the study is 'blinded'. Blinding helps to ensure that everyone taking part is treated in the same way, so that that the comparison between aspirin and standard of care is as accurate as possible.

What if my doctor needs to know which treatment I am on?

If your doctor feels that they need to know which treatment you are on, then your doctor will be able to find out. For example, if there has been an overdose or an emergency surgery. If you have a planned surgery coming up, then please let your doctor know and we can pause the medication and restart it again afterwards.

What hospital visits will be required?

There are 4 different types of visits and a phone call:

1. Screening visit
2. Collection visit
3. 1-month phone call
4. 6-monthly visits for 5 years. (This may coincide with your routine clinical care if your clinician decides this is appropriate. Otherwise, this visit would be a research visit as part of the above study.)
5. End of treatment visit

Table 1 at the end of this information sheet gives more information about the procedures and tests in each assessment.

Step 1: Consent and Screening Visit:
(Extra visit)

If you are interested in joining the study, you will be asked to sign and date the study consent form.

Step 2: Screening Visit

You'll be invited to attend the hospital to assess your suitability to take part.
This visit is important to ensure you're willing and happy to take part in the study, have signed your consent form and have completed the necessary tests to ensure you are suitable to take part.

You'll have:

- Questions about your health and medical history
- Temperature measurement
- Heart rate measurement
- Blood pressure check
- Respiration rate measurement (how fast you breathe a minute)
- Height measurement
- Weight measurement
- Clinical exam
- Listen to your heart and lungs
- Examination of your skin and abdomen
- Review of your last hospital blood test
- Review of all your medications
- A discussion about any symptoms or complications you have (if any)
- Questionnaires to be completed either at home or on the day of the visit
- 6 ml blood test for genetic studies in the future if you agree to this
- 43 ml blood and 10ml urine tests that will be stored and used for future research studies, if you agree to this. (43ml of blood is equivalent to 3 tablespoons of fluid).
- 5ml of blood to check how healthy the liver is.
- A non-invasive scan, called a Fibroscan, that measures scarring in the liver (if available at your local hospital)
- Review of your last scans
- Check you've had your annual colonoscopy and if not, your hospital team will arrange for it to be carried out within the next 60 days as part of your routine clinical care
- Your hospital team will check you have had the appropriate National Health Service (NHS) PSC monitoring (scans) and if not, this will be arranged.

What happens once you are confirmed suitable to take part?

Step 3: Collection Visit (Extra visit)

You will be asked to come in again after your screening visit. You will be randomly assigned to take either the aspirin or placebo tablets Your hospital team will give you 2 bottles of either aspirin or placebo tablets and each bottle will last you three calendar months.

Your hospital team will give you a Contact Card with an emergency contact number to call in case you feel unwell at any time. You should try to always carry this with you.

You take either one tablet of 75mg of aspirin or one tablet of placebo once a day with a glass of water and food for 5 years.

You will be given a patient diary to record how you feel, symptoms and the dates you have taken your tablets (aspirin or placebo).

You will also be given some questionnaires to take away and complete after a month.

Step 4: One-Month Phone Call

You will be called one month later to check how you are, and you'll be asked:

- Questions about your health and medical history
- A review of all your medications
- A discussion about any new symptoms or complications you have (if any)
- Review of your last blood tests
- Review of your diary card
- Check you have completed your questionnaires.
- You may be asked to post the one-month questionnaires back to your clinical team.

The clinical team may want to see you in person if you feel very unwell.

Step 5: Six-Month Visit
(Ideally this visit will be at the same time as your routine hospital visit and does not replace your usual care).

You'll have:

- Questions about your health and medical history
- Clinical exam
- Temperature measurement
- Weight measurement
- Heart rate measurement
- Listen to your heart and lungs
- Examination of your skin and abdomen
- Blood pressure check
- Respiration rate measurement
- A review of all your medications
- A discussion about any new symptoms or complications you have (if any)
- Review of your last blood tests
- Questionnaires to be completed either at home or on the day of the visit
- 43ml blood and 10ml urine tests that will be stored and used for future research studies, if you agree to this. (43ml of blood is equivalent to less than 3 tablespoons of fluid).
- Review of your last scans
- Your hospital team will check you have had the appropriate NHS PSC monitoring (scans, including Fibroscan) and annual colonoscopy) and if not, this will be arranged.
- You will be given a further 6 months of study medication in 2 bottles
- You will be given a stool sample collection kit annually to drop at your GP surgery (as part of your NHS routine clinical care)

Step 6: End of Treatment Visit
(Extra visit)

You'll have this visit after you have taken your last tablet. You'll have:

- Questions about your health and medical history
- Clinical exam

- Temperature measurement
- Weight measurement
- Heart rate measurement
- Respiration rate measurement
- Listen to your heart and lungs
- Examination of your skin and abdomen
- Blood pressure check
- A review of all your medications
- A review of your last scans
- Questionnaires to be completed either at home or on the day of the visit

After your end of Treatment Visit you will not be required to come back for any study specific assessments, but we will collect some medical data on you for a maximum of 5 years after you have taken your last tablet.

Are there any medications I cannot take whilst I am on the study?

If you are already on ursodeoxycholic acid (also known as UDCA or urso), the dose must have remained the same for 12 weeks before you start the study. Your doctor will check this before you start.

During the study you should not take the following drugs until it has been discussed with a health care professional:

- Another drug that could alter how your blood clots (what doctors call an antiplatelet or anticoagulant)
- Methotrexate at a dose higher than 15mg once per week
- Uricosuric agents such as probenicid and sulfinpyrazone
- Aspirin
- Long term use of Non-steroidal anti-inflammatory drugs daily for more than 3 weeks

  If you need to stop the study drug for any reason, please consult your physician and they will advise you.

Can I take aspirin if I am pregnant/wish to get pregnant or breastfeeding?

At the present time, low dose aspirin is considered safe in pregnancy. Therefore, there is no need to avoid or use additional contraception for this study. There is convincing evidence to show that low-dose aspirin (150mg or 75mg daily) protects against severe pre-eclampsia and foetal growth restriction if commenced before 16 weeks' gestation. Furthermore, other research has shown that there was no significant difference in the rate of congenital complications in those who were taking low-dose aspirin and those who were not. Thus, participants planning pregnancy, or those who become pregnant will not be asked to stop treatment. There is also no evidence to indicate that there are any risks associated with taking aspirin when breastfeeding. Additional information about your pregnancy and baby will be collected if you become pregnant while on the Asp-PSC study, and if you were to become pregnant or be breastfeeding during the study you can continue on study treatment. However, if you wished to discontinue or pause the trial treatment this is your choice, please speak to your research nurse or study physician.

4. What happens when my medication stops?

When the study stops you will continue with your usual NHS care, under your usual doctor who cares for your PSC and IBD and they will decide what treatment to prescribe for you if any.

5. Will I be compensated for taking part in the study?

You will not be paid for taking part in the study. However, for every study visit you attend you will be able to claim back reasonable travel expenses. Your hospital team will be able to give you more information on this.

6. Study treatment

During the time you receive study medication you will be examined regularly by your study doctor and hospital team and asked about potential side effects. You may want to use the diary card given to you by your hospital team to record any side effects and how you feel.

Your study doctor and hospital team will help you manage any side effects that you experience (if any), However, it is also important to report any side effects or changes to your general health to the study doctor or hospital team immediately.

If you have severe side effects from the study medication, your study doctor may ask you to stop taking it.

The following is a list of known side effects for aspirin.

- An increased risk of upper gastrointestinal bleeding and stomach ulcers (rare)
- Low grade stomach discomfort
- Skin rashes
- Increased bleeding
- Risk of asthma in those patients with nasal polyps
- Increased risk of blood loss at menstruation
- Mild kidney damage and water retention

If you have any major concerns or are feeling unwell, please contact your study doctor and hospital team immediately using the contact numbers at the end of this information sheet or alert card

7. What are the other possible disadvantages and risks of taking part?

Most of your study visits will ideally take place during your usual routine PSC care appointments and your hospital will let you know if there will be extra visits. There will be at least three in-person additional visits (Consent and Screening Visit, Collection Visit, and End of Treatment Visit). See table 1 for time needed for visits and assessments.

Blood and urine tests are taken regularly and possibly may cause you some discomfort or inconvenience.

Multiphase CT scans and ERCPs are part of your routine care. If you take part in this study you will not undergo any additional CT or ERCP procedures. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to you are the same, whether you take part in this study or not.

An MRI examination is not believed to have hazards associated with it when operated within the standard National Radiological Protection Board Guidelines, which is adhered to in NHS hospitals. You will receive a leaflet with this information sheet giving you information on "Having an MRI scan" at your local hospital.

MRI scans do not involve the use of radiation and is believed to be therefore non-hazardous as regards radiation exposure

During the MRI scan, you will lie on a table that slides into a large round tunnel. If you suffer from claustrophobia (fear of enclosed spaces) you will may find a MRI scan an uncomfortable experience and your doctor may feel this study would not be suitable for you.

There are some standard contraindications to having an MRI which will be reviewed by your medical team, such as if you have a pacemaker or implanted defibrillation device, metal fragments in the eyes or recent metalwork inserted in your body.

The MR scanner can also be noisy. This is normal and is the same for any images being taken this way. You will be offered ear protection if you wish to reduce the noise during the scan.

As part of your MRI scan you may be given a contrast agent (dye). It is extremely rare for patients to have an allergic reaction to the MRI contrast injection. However, if this were to occur, radiology departments are fully prepared to treat an allergic reaction and will do this without any delay. This may require you to stay in the department for a period of observation and we may decide to give you anti-allergy medications, which are always available in the MRI unit.

If you feel distressed at any point, a member of hospital team will be able to offer help.

If you have private medical insurance, please check with the company before agreeing to take part in the study. They will need to ensure that your participation will not affect your medical insurance.

8. What are the possible benefits of taking part?

The study researchers and your study doctor and hospital team cannot promise the study will help you directly. However, the information gained from the study may improve future treatment and management of people with PSC and IBD.

You will be closely monitored and cared for by an expert team of doctors and nurses and seen more regularly than if you decided not to take part.

9. What if there is a problem?

Your study doctor and hospital team will be there to answer any questions you might have regarding your PSC and its associated complications, in addition to your participation in the study. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during this study, then there will be several options available to you. Full details are included in Part 2 of this information sheet. If there is a safety concern, please use your Alert Card.

10. Will my taking part in the study be kept confidential?

Yes. The study researchers, study doctor and hospital team will follow ethical and legal practice and all information about you will be handled in confidence. Full details are included in Part 2 of this information sheet.

If the information in Part 1 has interested you and you are considering taking part in the study, please read the additional information in Part 2 before making your decision.

Part 2

1. What if new information becomes available?

Sometimes there is new information about the medication being studied. If new information becomes available, your study doctor will tell you and discuss whether this impacts your participation in the study.

If you decide not to carry on, your study doctor will make arrangements for your normal care to continue. If you decide to continue, your study doctor and hospital team may ask you to sign an updated consent form.

2. What will happen if I don't want to carry on with the study?

You must tell your study doctor and hospital team immediately if you no longer wish to take part in the study. Your study doctor will discuss options for further treatment with you.

Your rights to access, change or move your information are limited, as the study researchers, your study doctor and hospital team need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, no new information will be collected about you, but information already collected will be kept including any research samples unless you specifically withdraw your consent for this.

To safeguard your rights, the minimum of personally-identifiable information will be collected for the purposes of the study.

3. What if there is a problem?

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 London 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 on +44 (0)203 312 6454/6254. The normal National Health Service mechanisms are also available to you. Details can be obtained from your study doctor or nurse. If you are still not satisfied with the response, you may contact the Imperial College Research Governance and Integrity Team.

If you take part in the study, a telephone number shown on your Alert Card will be provided in case you need to contact your study doctor and hospital team. If there is a medical emergency, please inform them as soon as possible. If necessary, you may be withdrawn from the study, and offered whatever treatment is appropriate.

Any complaint about the way you have been dealt with during the study or any possible harm you

might suffer will be addressed fully. Taking part does not affect your rights as a patient.

If you have a concern about any aspect of this study, you should ask to speak to the study doctor who will do their best to answer your questions. You can use the contact details at the end of this information sheet.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, you can do this through the NHS complaints procedure. In the first instance it may be helpful to contact the Patient Advice and Liaison Service (PALS) at your hospital or Patient Advice and Support Service (PASS) for participants in Scotland (see contact details below).

Any unexpected results will be checked by the study doctor. They will decide if these results need to be looked into further by the local medical team, a different hospital team, or your regular doctor.

4. How will information about you be used?

Research Study Title: Asp-PSC
IRAS no.: 1007320

Imperial College London is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for:

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

This study is expected to finish in July 2034.

For more information regarding the end date please contact the study team, see 'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED' for contact information.

We will need to use information from your medical records for this research project. This information will include your month and year of birth and NHS number or Community Health Index (CHI) for participants in Scotland

We will record some demographic data such as age, sex and gender. You can choose to share other personal information, like your sexual orientation or religion, but this is optional.

People within the Imperial College and study team (see section for sharing your information with others) will use this information to do the research or to check your records to make sure that the research is being done properly and the information held 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 unique code number (study Identification) instead, and this code will also be used to label urine and blood samples.

We will keep all information about you safe and secure.

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.

LEGAL BASIS

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 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) rely on "scientific or historical research purposes" or "statistical purposes".

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

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.
- The following Research Collaborators / Partners in the study:
  - Cancer Research UK, who fund the study. The following data is shared with them in this capacity as part of an agreement with Imperial College London, as well as ensuring

appropriate oversight of any serious side effects that you and other study participants may experience:
  - Results data used to write reports from the study, specifically on how effective and safe the study treatment is;
- Norfolk & Norwich University Hospitals NHS Foundation Trust who are storing blood and urine samples. The following data is shared with them to enable this:
  - Sample data, including participant study IDs, month and year of birth and hospital you attend;
- Infinitt Europe GMBH are storing your data from routine scans. The following data is shared with them to enable this:
  - Your Trial identification number
  - Date of scan upload
  - Type of scan
- Imperial College London who are analysing the results. All study data is shared with them.
- iQur who will be processing a test called Enhanced Liver Fibrosis. They will see the study ID, month and year of birth, and hospital you attend.
- St George's University Hospitals NHS Foundation Trust, Black Country Pathology Services, Cambridge University Hospitals may also process the ELF test. They will see the study ID, month and year of birth, and hospital you attend.
- UK ethics and regulatory authorities who are required by law to approve and oversee research. The following data is shared with them to ensure appropriate oversight of any serious side effects that you and other study participants may experience:
  - Data about serious side effect/s, including whether they got better;
  - Data about medications taken and whether these were to treat the serious side effect/s or were other medications that were being taken at the time the serious side effect/s occurred.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study 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, used against you or used to make decisions about you.

COMMERCIALISATION

Samples and 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 and 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 because some research using your data may have already taken place and this cannot be undone.

- If you choose to stop taking part in the study, we would like to continue to collect information about your health from your hospital. If you do not want this to happen, tell your study doctor and hospital team and we will stop. This will not affect any healthcare or support you may be receiving separately.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.
- 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. Samples will be stored at Norfolk and Norwich Biorepository.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to asp-psc@imperial.ac.uk

COMPLAINT

If you wish to raise a complaint on how we have handled your personal data, please contact the research team first by sending an email to asp-psc@imperial.ac.uk.

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.

5. Involvement of the General Practitioner / family doctor (GP)

With your permission, indicated on the consent form, your hospital team will inform your GP about your involvement in this study.

6. What will happen to any samples that I give?

Blood samples for safety

These blood samples will be taken and tested by your hospital to check it is safe for you to be taking aspirin. These will be destroyed immediately after testing.

Blood sample to check the health of your liver

This blood sample will be sent to iQur Laboratory, St George's University Hospitals NHS Foundation Trust, Black Country Pathology Services, Cambridge University Hospitals.

Research Blood samples and Urine samples

These blood and urine samples will be processed at your hospital and then sent to the biorepository called Norfolk and Norwich Research Park Biorepository.

7. What will happen to the results of the research study?

Your study doctor, the study researchers and the sponsor (Imperial College London) plan to publish the results of this study in a scientific journal and/or present them at national and/or international meetings, so that the information will be widely available to all. Clear, understandable summaries will be published on websites. You will not be personally identified in any publications or reports. PSC Support will also publish a summary of the results on their website and social media accounts.

8. Who is organising and funding the research?

Imperial College London is the legal sponsor of this study and is organising the study through the Cancer Research UK Imperial Centre: Clinical Trials Section. Funding is being provided by Cancer Research UK.

The sponsor of this study will pay your hospital for including you in this study, but your study doctor and hospital team will not receive any personal financial payment if you take part.

9. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by Wales Research Ethics Committee 1 Cardiff.

10. Further information and contact details

If you have any questions or concerns about this study, including study-related injury or study treatment queries, you can talk to <insert name of doctor and tel.no> or <insert name and tel. no.>.

This study is also listed on the Cancer Research website and can be found here: CRUK's clinical trials database.

(Only applicable to a site has a 24 hour number) Please contact the xxx on the following 24 hour contact details:

Name:
Telephone:

You may also wish to contact PSC Support, the UK patient organisation for patients with PSC.

- www.pscsupport.org.uk
- PSC Support, Unit 23056, PO Box 4336, Manchester, M61 0BW or
- hello@pscsupport.org.uk

Thank you for taking the time to read this information sheet.

If you decide you would like to take part, you will be given a copy of this information sheet to keep together with a copy of your signed consent form.

Table 1: The table below shows a list of the study activities and procedures undertaken as part of your routine clinical care.

Activity	Explanation	Estimated time for activity
Medical history and medication reviews	You will be asked questions about your current and previous health, including when you were diagnosed with PSC and IBD. Each time you will be asked about any medicines you are taking, whether prescribed or bought from a pharmacy, including over-the-counter medicine, vitamins and herbal treatments. We recommended that you keep a list of any medications you are taking and bring it with you to each visit.	20 minutes (included in Study Visit timing)
Physical examination	The study physicians will listen to your heart, lungs and examine your skin and abdomen to monitor your health and wellbeing if required to do so during the Study Visits.	10 minutes (included in Study Visit timing)
Study Visits	Study Visits will take place at the hospital and are an opportunity to talk to you about your health and wellbeing, your disease in general, how you are finding the study medication and being part of the study. We'll	Approximately 1 hour

	also perform some of the other tests and activities in this table.	
Issuing you with the study medication	At your Collection Visit and at every 6 month follow up you will be given 6 months' supply of study medication. You'll be randomly allocated either aspirin or placebo tablets for the duration of the study.	
Adverse Events	You will be closely monitored during the study. You should let your study doctor or nurse know immediately if you notice any major changes in your general health between Study Visits and if you have any concerns regarding the study. If you are admitted to a hospital between Study Visits for any reason you must inform your study doctor and/or nurse as soon as possible. You will be provided with the telephone number and email address for contacting your study team.	5 minutes
Blood tests	These blood tests will help monitor your health and wellbeing whilst you are taking either aspirin or the placebo for the duration of this study. A sample of your blood will be used to determine how healthy your liver is at the Screening Visit.	5 minutes
Optional urine tests	A urine test will be collected from you for use in future research into PSC (if you agree to this).	5 minutes
Stool test	A sample of your stool will also be tested for levels of inflammation in your gut. This is called faecal calprotectin. A faecal calprotectin test will be done every 12 months whilst you are taking either aspirin or placebo.	5 minutes

Optional additional blood tests	An extra blood sample will be taken from you if you agree for use in future research.	5 minutes
Fibroscan (if available at your hospital)	This is a special type of ultrasound machine that measures the stiffness of your liver, often referred to as a Fibroscan. However, rather than generating a picture, the Fibroscan machine provides a measure of liver stiffness which will help us understand the condition of your liver. If you are feeling worried about the test or result then your research nurse or physician can talk you through the process and help you understand the results.	15 minutes
Magnetic resonance cholangio pancreatography (MRCP) , Magnetic resonance imaging (MRI) and Ultrasound scans	During your normal routine care you may have a special type of MRI scan called a MRCP or an MRI where some dye is injected into your vein. You may have an ultrasound scan of your liver and gallbladder. MRCP stands for magnetic resonance cholangiopancreatography. This is a scan that uses magnetic fields to create detailed pictures of your pancreas, bile ducts and gallbladder and will enable us to monitor your PSC. The ultrasound and MRCP/MRI scans will be carried out as part of your routine NHS care for PSC. We'll record the results from this investigation during the duration of the study and may ask for a copy of the images. All results will be made available to you by your local treating physician.	45 minutes
Computerised tomography (CT) scan	As part of your routine NHS clinical care, you may have a special test called a CT scan. This is where some dye (called a contrast) is injected into one of your veins. The scan uses radiation to help create a picture of your internal organs that need to be assessed by your specialist. For patients with PSC, these scans are only done for certain indications. Although this trial does not request that you have CT scans done as part of the trial, it is possible during the duration of the study your NHS consultant may request one for you. We'll record the results from this investigation during the duration of the study and may ask for a copy of the images. All	5 minutes

	results will be made available to you by your local treating physician.	
Endoscopic retrograde cholangio pancreatography (ERCP)	As part of your routine NHS clinical care you may have a special test called an ERCP. This is a camera test where contrast (a dye) is introduced into your bile duct and, in PSC, various things can be done to help improve symptoms and help make additional diagnoses. To create these pictures, ionizing radiation is used. Although this trial does not request that you have ERCPs as part of it, it is possible during the duration of the study your NHS consultant may request one for you. We'll record the results from this investigation during the duration of the study and may ask for a copy of the images. All results will be made available to you by your local treating physician.	40-60 minutes
Colonoscopy	A colonoscopy is a test that uses a narrow, flexible tube with a light on the end and a tiny camera to look at the inside of your bowel. The tube is placed in your bottom to look for inflammation. Very small samples (the size of a pin head) of the inner lining of your bowel will be taken during your colonoscopy called biopsies. This test is performed by a trained professional. Your yearly colonoscopy will be carried out as part of your routine NHS care for PSC and IBD, and your results will be recorded as well as the results from any biopsies taken. This will avoid you having to have unnecessary extra colonoscopies for the study. All results will be made available to you as part of your normal routine treatment.	45 minutes
Patient questionnaires	It is important for us to understand how aspirin affects the way you feel. Some treatments can make people feel better, but others can cause symptoms or side-effects that make people feel worse. You'll be asked to fill in questionnaires to assess your symptoms and quality of life relating to your PSC. These should be filled in at home and bought with you to your hospital visits. We will be using the following questionnaires: ▪ The 5D-itch Questionnaire has questions to find out about any itching you may have. ▪ The Primary Sclerosing Cholangitis-Patient Reported Outcome (PSC-PRO) Questionnaire has	10 minutes

	29 questions used to find out about how you feel and how symptoms affect you. ▪ Short Form (SF)-36 has questions to find out about your quality of life. ▪ The Short Inflammatory Bowel Disease Questionnaire (SIBDQ) has questions about the activity of your colitis (IBD) ▪ Patient Report Outcome-2 (PRO2) has questions about stools and bleeding. ▪ Chronic Liver Disease Questionnaire (CLDQ-PSC) has questions about how you have been feeling over the last 2 weeks. It is important that no one else fills in these questions for you, as we really want to understand your point of view.	
Counting previous study medication	At each 6-monthly Study Visit, you will need to bring in previous study medication bottles. We need them to count and dispose of any unused tablets.	5 minutes

Table 2

This table shows all the abbreviations within this document.

CLDQ-PSC	Chronic Liver Disease Questionnaire-primary sclerosing cholangitis
CT	Computerised Tomography
EEA	The European Economic Area
ERCP	Endoscopic Retrograde Cholangio Pancreatography
GDPR	General Data Protection Regulation
GP	General Practitioner
IBD	Inflammatory bowel disease
ID	Identification
MRCP	Magnetic Resonance Cholangio Pancreatography
MRI	Magnetic Resonance Imaging
NHS	National Health Service
PALS	Patient Advice and Liaison Service

PASS	Patient Advice and Support Service
PRO2	Patient Reported Outcome 2 Questionnaire
PSC	Primary sclerosing cholangitis
PSC-PRO	Primary sclerosing cholangitis- Patient reported Outcome Questionnaire
SF-36	Short Form-36 Questionnaire
SIBDQ	The Short Inflammatory Bowel Disease Questionnaire
UDCA	Ursodeoxycholic acid
UK	United Kingdom