

Video Explaining COLLABORATE

A link to the animation can be found here: https://youtu.be/H0va_REe8Tw

In this short animation, we'd like to explain the COLLABORATE study

Narrator: "Meet Sharon and her baby, Ali who was born 12 weeks early and is now receiving care in the neonatal unit."

Sharon (thinks): "I want to do everything I can to help Ali grow and get stronger so I'm expressing milk regularly for him."

Doctor (talking to Sharon): "You're doing brilliantly at expressing milk for Ali but we understand expressing can be difficult. Sometimes Mum's find they can't express enough though this is usually just for a short time. Therefore we use top up feeds. In the UK some neonatal units use pasteurised donor milk for top-ups, and some use formula. We don't know which is best. Therefore, I'd like to tell you about a research study called COLLABORATE. COLLABORATE will find out which is the best treatment."

Sharon: "When my sister was expressing milk the doctors added something called fortifier, why is that?"

Doctor: "That's the second question the COLLABORATE study will resolve. For preterm babies born very early like Ali, we wonder if human milk may not have enough nutrients, so some doctors add extra protein and carbohydrate, called fortifier, to their feeds. Fortifier is a powder made from cow's milk. Others wonder if routinely adding fortifier could result in overfeeding or might irritate a baby's gut."

Narrator and text on screen:

- **Pasteurised human donor milk** has been pasteurised, that is, heat treated, to remove the risk of infection but this destroys or reduces the protective factors in breastmilk that support immunity and brain development. Donor milk is also lower in nutrients than milk from a baby's own mother.
- **Preterm formula** is made from cow milk and contains consistent levels of nutrients, but some doctors wonder if this might increase the risk of necrotising enterocolitis, an inflammation of the gut.
- **Fortifier** is made from cow milk and can help babies grow stronger but might result in overfeeding.

Visual: Necrotising enterocolitis is a gut condition that mainly affects preterm babies and can be very mild or very severe. In severe cases surgery is needed to remove diseased gut. In the UK, 3-4 in a hundred babies born more than 8 weeks early develop severe NEC. Of these about half have only had human milk feeds and about half have had some formula or fortifier.

Doctor (talking to Sharon): "Because we don't know whether to use top-ups of pasteurised donor milk or formula, or whether or not to add fortifier, we are taking part in the COLLABORATE study. In COLLABORATE each baby will have an equal chance of getting either **pasteurised** donor milk or formula if top-ups are needed, and routinely having fortifier added to human milk or not."

Visual: COLLABORATE will give every baby an equal chance of getting either pasteurised donor milk or formula if top-ups are needed, and routinely having fortifier added to human milk or not. This equal way of getting either treatment is called randomisation.

Sharon: “Why is this study called COLLABORATE?”

Narrator: "The COLLABORATE study was designed because parents and clinicians want answers to these questions as soon as possible so that every baby gets the best treatment. Parents helped in all aspects of the study and chose the name COLLABRATE because it's only by working together that we can resolve these important uncertainties in how we care for preterm babies. We will need just over 3000 babies to take part in COLLABORATE to get a clear answer to the questions.

Sharon: “So Ali will not be given any new or experimental treatments?”

Doctor: "No, the study doesn't introduce any new treatments, all the feeding methods are already widely used"

Sharon: “I'll discuss COLLABORATE with my partner, but I think we'll agree for Ali to take part. I want him to have a fair chance of getting the right treatment even though we don't yet know what this is. And I want future babies to be able to have the best treatment. But will you need to collect a lot of extra information for the study?

Doctor No, we won't need to; COLLABORATE is a very efficient study because the information needed will come out of the baby's record in the National Neonatal Research Database, the NNRD. Let me tell you about the NNRD now.”

Text on Screen: Watch this brief video to find out more about the NNRD

There is more information about the COLLABORATE study here: QR code/
collaborate@imperial.ac.uk

We'd like to thank Alima, Louise and Rafika. Parents of babies born either preterm or sick for helping make this video