

## Participant Information Sheet aged 6-11 years



Mitochondrial DAMPs as mechanistic biomarkers in paediatric Crohn's disease

### ***Mitochondrial DAMPs as mechanistic biomarkers of mucosal inflammation in paediatric Crohn's disease and Ulcerative Colitis (Mini-MUSIC)***

Hi! We are inviting you to take part in our research study. Research tries to answer questions and make treatments better for people who are unwell. Please read the following leaflet. Talk to your family, doctor, and nurse if you would like to. If something doesn't make sense or if you have any questions please let us know. This study has been checked and approved by Health and Social Research Ethics Committee A (HSC REC A). They made sure this study is important to do and is safe.

#### Why are we doing this research?



This research study is into Crohn's disease (CD) and Ulcerative Colitis (UC). Both can give people a sore tummy (gut). It means they might need to go to the toilet many times a day. People may have blood in the stool (poo). It can make the person feel sleepy and not have much energy. This can make people miss out on school, sport, family activities and other fun.

Medicine is used to heal the sore gut in people with CD and UC. Medicine helps make the sore gut healthy and normal again. Full healing of the sore gut is the goal. When the gut is fully healed you will have less tummy soreness, will have more energy and toileting will return to normal.

We have very good medicines to heal the sore gut in CD and UC. Right now we do not have the best tests that can tell how much the gut has healed without looking inside the gut using a special camera. This special camera test (endoscopy and colonoscopy) is a big test that involves a child to come into hospital for the day and sometimes overnight. It also involves a special medicine that is given so the child is asleep and does not feel the camera test being done. Doctors looking after children only do these camera tests when absolutely necessary.

We need better tests to tell us just how much the gut is healing that does not involve camera tests (endoscopy and colonoscopy).

### What is the purpose of the study?

The Mini-MUSIC Study wants to find out if a new blood and stool (poo) test can tell us how well the gut (tummy) is healing. This study will see if these new tests are better than the tests we use today.

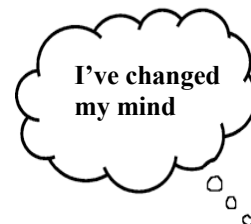
There are special structures in the cells of our body called Mitochondria. These are the batteries of our cells. They make the energy to keep cells healthy. In people who have CD and UC, these mitochondria become damaged. The damaged mitochondria sends out specific signals that cause the gut (tummy) to be unwell.

The new blood and stool test will measure these specific signals. We will learn more about how the damaged mitochondria signals work inside the body.

If you choose to take part, the research team will see you at study visits and closely watch how your IBD is doing over one year.

### Do I have to take part?

No, you don't. Talk to your parent/guardian about it. It is your choice whether you take part or not. You can always change your mind at any time. Nobody will be upset with you if you don't want to do it.

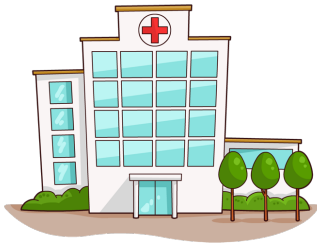


## What do I need to do if I take part?

Your parent/guardian will read information about the study and sign a consent form allowing you to be part of the study.



The study lasts one year. It involves 3 hospital visits. At each hospital visit you will be with your parent/guardian.



You will come to the hospital at the start of the study. You will come back around 3 months and then again at 1 year.

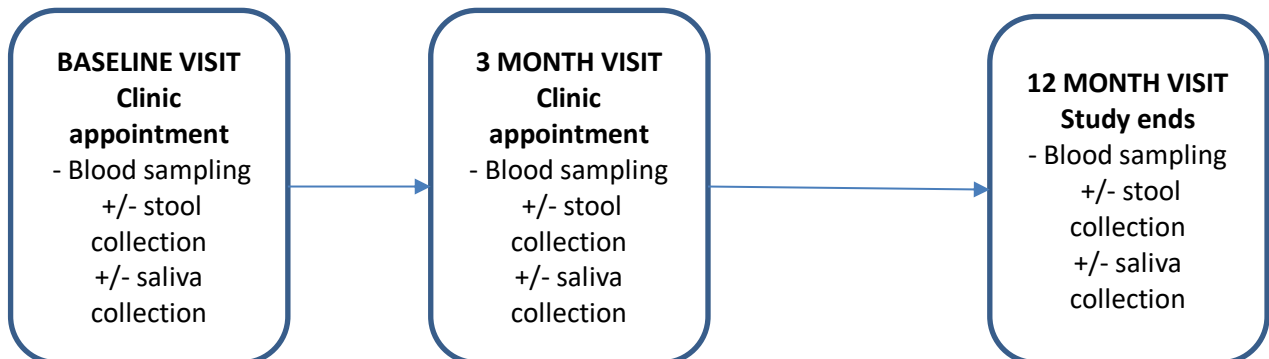
At each visit we will ask questions about your health and IBD.

We will carry out a blood test, a stool (poo) test and ask you to give a saliva (spit) sample.



We will try to do the research blood test at the same time as you are having your regular IBD blood tests.

### Overview of involvement



## Is there anything else I need to do?

We would ask you or your parent/guardian to contact the research team if you:



- A. Are admitted to hospital for your IBD
- B. Are going to have a special camera test (endoscopy or colonoscopy)
- C. If you are coming into hospital for an appointment for your IBD. We will try to coordinate your study visit so you are not making extra trips to hospital.

## How will it affect me?

It should not affect you in a bad way. You might even enjoy taking part in a research study.

You may feel some pain or see a small bruise after having a blood test. We will aim to do the study blood test at the same time your regular blood test are done.

We will let your GP know that you are taking part in the study. We will give your parent/guardian travel money to cover the costs of getting to the hospital for any extra visits you may have during the study.

## How will we use information about you?

We will need to use information we get from you and your parent/guardian. We will use information from your medical records.

All the information we collect during the study will be kept confidential. Information will include your initials, name, NHS number, both your and or your parent/guardian's phone number, and mail addresses. People who do not need to know who you are will not be able to see your name. Your information will have a code number instead.

People will use this information to do the research. And to check your records to make sure that the research is done properly. We will keep all information about you safe and secure.

### **What happens when the study is finished?**

You will continue to see your normal IBD doctor and team at your hospital.

We will write our reports in a way that no-one can work out that you took part in the study.

Non-named information and samples will be stored securely for a minimum of 5 years following the rules for research studies.

Your stool (poo), blood, saliva and any biopsy samples will be stored securely at the Centre for Inflammation Research, Queens Medical Research Institute, Edinburgh.

Some of the anonymised data and samples saved from the study may be used as part of future research.

### **What happens if I don't want to take part anymore?**

Just tell your parent/guardian and someone from the research team that you don't want to take part any more. You don't have to give a reason, it is YOUR choice. If you stop taking part we would like to continue collecting information about your health from your health record. If you do not want this to happen, tell us and we will stop.

If there is a problem you can talk to your parent/guardian. You can also talk to any member of the research team at email [miniMUSIC@](mailto:miniMUSIC@)

***Thank you for reading this!***

***If you have any questions, please talk to your parent/guardian, the nurse or doctor who gave you this.***

