

Participant Information Sheet aged 12-15 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 improve how people are treated when they are unwell. Please read the following leaflet. Talk with your family, doctor, nurse and let us know if you have any questions.

This study is co-organised and supervised by the University of Edinburgh, your hospital and the paediatric gastroenterology departments at the Royal Hospital for Children and Young People in Edinburgh. This study has been checked and approved by Health and Social Care Research Ethics Committee A (HSC REC A). They have made sure this study is important to do and is safe.

Why are we doing this research?



This research 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 a lot of times a day, and have blood in the stool (poo). It can also make the person feel sleepy and not have much energy. These 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 gut is the goal. This will help bring back normal toileting, energy levels and keep the gut healed for a long time.

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 exactly how the gut is healing that does not involve camera tests (endoscopy and colonoscopy).

What is the purpose of the study?

There are special structures in the cells of our body called Mitochondria. These are the batteries of our cells, making the energy to keep cells healthy and alive. In people who have CD and UC, these mitochondria become damaged and act like a faulty battery. The damaged mitochondria sends out specific signals that tell the body to create more inflammation. We believe this is one reason the gut in people with IBD gets sore and unwell.

The Mini-MUSIC Study will test how well a new blood and stool (poo) test are in telling us about how the gut is healing. These two tests measure the number of mitochondria signals there are. We want to find out if low numbers of these tests tell us the gut is more healed and if high levels of these tests tell us the gut is less healed and is more unwell. This study will compare these new tests to the tests used today by doctors. This study will see if these new tests are better than the tests we use today.

In this study, we will also learn more about how the damaged mitochondria signals work inside the body. We will learn about how they can tell us about all the different amounts of inflammation inside the gut.

If you choose to take part, the research team will see you at 3 study visits and closely watch how your IBD is doing over one year.

Why am I being asked to take part?

You have been asked to take part as you are 12-15 years old and have either Crohn's Disease or Ulcerative Colitis. You are being treated at one of the hospitals taking part, and you are feeling unwell at the moment.

Do I have to take part?

No. It is up to you. Talk to your parent/guardian about it. If you decide not to take part, no one will be upset with you. This will not affect how doctors and nurses look after you now or in the future.

If you do decide you would like to take part, you will be given this information sheet to take home and keep. We will ask that you write your name on a form called an assent form which would mean you are happy to take part. We will also ask your parent or guardian if it is okay for you take part and they will sign a form called a consent form.

What will happen if I take part?



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

Taking part in this study will mean you will come to the hospital for 3 study visits. We will try to coordinate these study visits for when you are coming to hospital anyway for your IBD care. There is one study visit at the start called the baseline visit, another visit 3 months later and a final study visit at 1 year.

Together with your regular IBD blood and stool (poo) tests, we will ask you to do a research blood test and optional stool (poo) and saliva (spit) test at each study visit. We will tell your IBD doctor what the test results are. These results may help your doctor care for your IBD.

You will continue to be looked after by your regular IBD doctor and team. They will continue to decide what medicines are best for helping your IBD.

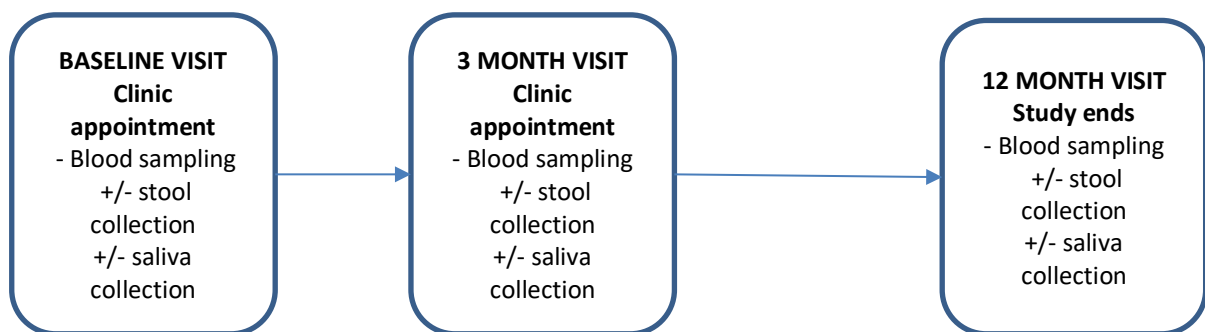
If your doctor decides a camera test is needed during the one year you are participating in the study, we would ask that you tell us. We will record these test results into the study. If

you are needing a camera test, we would ask for research biopsy samples to be taken when this test is being done. This would provide information about how your gut is healing.

If you come into hospital to stay overnight for your IBD during the one year you are participating in the study, we would ask that you tell us. We will record this information and any test results from this hospital time into the study. We may ask you to do another research blood and stool (poo) test while you are in hospital. This would provide information from when you are unwell in hospital.

A similar study is being done in adults who have IBD. We will learn more about these new tests by looking at both the results in adults with IBD and in children and young people with IBD.

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.

What are the possible benefits of taking part?

You may not get a direct benefit but it will mean your IBD will be very closely monitored during the study. Being involved in a research study can be like having a 2nd pair of eye on your condition running together with your normal treatment.

Some participants may get some satisfaction that they may be helping other people in the future with IBD.

We will give travel money to cover the costs of getting to the hospital for any extra visits you may have during the study.

What are the possible disadvantages of taking part?

There may be some pain or bruising from having a blood test taken. Most people with IBD need blood tests to check how well medicines are working. We will aim to do the study blood tests at the same time your regular blood test are done.

We know more of your personal time is being asked to come to the study visits. We will try to make these study visits at the same time as your regular IBD appointments.

What if there are any problems?

If you have a concern about any aspect of this study please contact The Mini-MUSIC Research Team at miniMUSIC@ who will do their best to answer your questions.

Can I stop taking part?

Yes. You are free to stop taking part in the study at any time without giving a reason. Just tell your parent/guardian, doctor or nurse. Nobody will be upset with you and this will not affect the normal treatment you receive. If you withdraw from the study 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.

What happens when the study is over?

When the study is over, you will continue with your normal CD or UC care at your hospital.

Will my taking part be kept confidential?

How will we use information about you?

We will use information from you, your parent/guardian, from your medical records for this study. This information will include your initials, name, NHS number, both your and your parent/guardian phone number, and mail addresses. People will use this information to do the research or to check your records to make sure that the research is being done properly.

All the information we collect during the study will be kept confidential. There are strict laws which protect your privacy at every stage. We will keep all information about you safe and secure. People who do not need to know who you are will not be able to see your name. Your data will have a code number identifier instead. When we have finished the study, all the anonymised information obtained from the Mini-MUSIC study will be stored securely for a minimum of 5 years following the regulatory rules.

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

We will write our reports in a way that no-one can work out that you took part in the study. Some of the anonymised data and samples saved from the study may be used as part of future research.

What are your choices about how your information is used?

You can stop being part of the study at any time. You do not need to give a reason. We will keep information about you that we already have

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.

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 the mini-MUSIC team: 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.

accord

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