



Study for treatment of severe eczema

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Young Person's Information Sheet (11-15 years)

Why are we doing this research study?



We are doing this study (called TREAT) to find out which is the best medicine to give children and young people who have severe eczema.

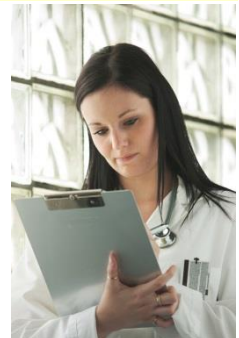
What is being tested?

The two medicines that are being tested in this study are called Methotrexate and Ciclosporin. These medicines are not new and are already used in the treatment of children and young people who have severe eczema. We would like to find out which is the best to use.

Why me?

You have been diagnosed with severe eczema which is difficult to manage and your hospital is taking part in the study.

We would like to involve 102 children and young people aged between 2 and 16 years. The information from this study will help us to improve how we treat children and young people who have severe eczema.



What will happen if I take part?

You will be in the study for a total of 15 months. You will be asked to take the study treatment for the first 9 months. You will have one more visit to your hospital clinic than you would usually have.



You will be told at your second visit whether you are in the group taking Methotrexate or Ciclosporin. To make it fair, no-one will pick which of the two medicines you are going to be given. It will be decided by a computer. You have the same chance of getting either medicine.

You may need to have an X-ray on your chest before taking any study medicine to check you are healthy.

The following will happen at most visits:

- Your eczema will be assessed
- You will be asked to fill in some short forms about how you are getting on
- Your blood pressure will be taken
- Your height and weight will be measured
- You will be given some more study medicine

If you are in the Methotrexate group, you will be asked to take the medicine (either as a tablet or an injection) once a week. If you are in the Ciclosporin group you will be asked to take the medicine (as a tablet) twice a day. If you are in the Methotrexate group you will be asked to come to the hospital for one more visit than the Ciclosporin group.

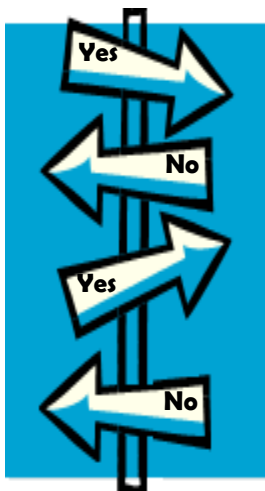
During the time you are receiving the study medicine you will be asked to give a blood sample at your clinic visits. You can have a cream or spray to numb the skin first if you would like. The blood samples will be used to check how you are getting on with taking the medicine. You will also be asked to give a urine sample every 3 months during the time you are receiving the study medicine. At the last visit, you will also be asked to give a blood sample and a urine sample. We will also ask if you can give a saliva sample at one visit.

At some of the visits, we will also use a sticky tape to collect cells from the surface of your skin. This does not hurt. It's just like putting sticky tape on your skin and gently lifting it up.

You will be asked to fill in a diary at home to keep a record of how you are getting on with the study medicine and your eczema. You will also need to record when you have taken your study medicine.

You will still be able to use your eczema creams whilst you are taking part in the study.

Do I have to say yes?



No not at all. It's completely up to you. We only want you to take part if you want to. Just tell us if you don't.

If you decide not to, don't worry, it won't change how you are looked after.

If you decide to take part, you will be given this leaflet to keep. You will be asked if you would like to sign a form to say that you understand what will happen and that you are happy to take part. Your parent/carer(s) will also have to sign a form to say they are happy for you to take part.

If you decide to take part that would be really helpful. If you then change your mind, that's OK as well - you can, and don't have to say why if you don't want to.

Are there any risks to taking part?



There are no more risks in taking part in the study compared to not taking part. These medicines are already used in normal care, but like other medicines sometimes they have unwanted symptoms (side effects). The research team will keep a close eye on you by doing some tests to check how you are getting on with taking the medicines and to check if there have been any side effects.

If you are in the **Methotrexate** group, you could get some of the following side effects:

- Feeling sickly
- Feeling tired
- Headache
- Indigestion (upset stomach)
- Diarrhoea (loose poo)
- Sore mouth or sore throat
- Loss of appetite (don't feel like eating)

If you are in the Methotrexate group, you should not take Ibuprofen as the two medicines can cause harm if taken together.

If you are in the **Ciclosporin** group, you could get some of the following side effects:

- Headache
- Shakiness
- Feeling sickly, diarrhoea (loose poo), tummy pain
- Tiredness
- Fever
- Acne
- Muscle cramps and muscle pain
- Pins and needles
- Hair growth on the face or body
- Sore gums

When you start taking the medicines it can sometimes lower the number of blood cells found in your blood which help you fight off infection and help stop bleeding and bruising, so you could be more likely to get an infection. The medicines could also affect your liver and kidneys but the research team will monitor any changes in your blood, liver and kidneys regularly. If you do get any side effects they usually go back to normal when you stop using the medicines.

If you notice any side effects it is important to tell your parent or the grown up who looks after you straight away so that they can tell your research doctor.

It is possible that if the study treatment is given to a pregnant female it could harm an unborn baby. You must **not** take part in the study if you are pregnant; neither should you if you plan to become pregnant during the study. We will test your urine to see if you are pregnant. Both males and females (who are sexually active) taking part in the study must agree to use contraception (a way of preventing pregnancy) whilst they are receiving the study medicine and for 6 months after the study medicine has been stopped. Any female who finds that she is pregnant while taking part in the study should tell her research doctor straight away. Any male whose partner becomes pregnant while taking part in the study should also tell his research doctor straight away.

Are there any benefits of taking part?

We cannot promise the study will help you, but both medicines have been shown to improve eczema in most cases. We hope that the information we get from this study will help other children and young people to get the best treatment in the future.

Who is doing this research?

The study is being run in your hospital, and is being organised by King's College London and Guy's and St Thomas' NHS Foundation Trust and the University of Liverpool.



Who can I ask about this?

Your mum, dad or the grown up who looks after you have been given lots of information. If you have any questions please ring: (INSERT NAME AND NUMBER FOR LOCAL NURSE)

Thank you very much for taking time to read this. Please ask any questions if you need to.



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Assent Form for Young People (11 – 15 years)

To be completed by the young person and their parent/guardian)

Please circle all you agree with:

(Young person)

- Has somebody explained this study to you? **Yes / No**
- Do you understand what the study is about? **Yes / No**
- Have you asked all the questions you want? **Yes / No**
- Have you had your questions answered in a way you understand? **Yes / No**
- Do you understand it's OK to stop taking part at any time? **Yes / No**
- Are you happy to take part? **Yes / No**

If any answers are 'no' or you **don't** want to take part, **don't** sign your name!
 If you do want to take part, please write your name and today's date

Your Name:

Today's Date:

Your parent or guardian must write their name here too if they are happy for you to do the study

Parent Guardian Full Name: Parent/Guardian Signature: Today's Date:

The researcher who explained this study to you needs to sign too:

Researcher Full Name: Researcher Signature: Today's Date:

When completed, 1 (original) to be kept in researcher site file, 1 copy each for medical notes; for patient and for CTU, University of Liverpool