TURTLE

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Child 11-15 Information Sheet for TURTLE

Invitation

We would like to invite you to take part in a research study. We will be trying to find out whether a medicine called Secukinumab when used with methotrexate (MTX) or mycophenolate mofetil (MMF) will help improve symptoms of Juvenile Idiopathic Arthritis (JIA) associated uveitis. Before you decide to take part, we would like you to understand why we are doing the research and what you will have to do if you would like to take part. The researchers doing this study have a lot of experience running previous studies looking at treatments for JIA uveitis.

Why have I been invited?

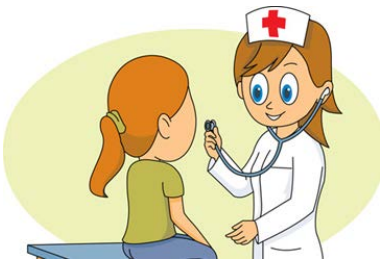
You have been asked to take part because you have uveitis associated with your JIA or chronic anterior uveitis and other medicines haven't helped your eyes get better. We will be asking another 49 children and young adults from all over the UK who have the same condition as you to take part in the study too.

Do I have to take part?

No. It is up to you whether you would like to take part or not and nobody will be upset with you if you don't want to. You can decide not to take part even if your parents or guardians give their permission for you to take part.

What will happen if I take part?

If you and your parents/ guardians agree for you to take part you will be asked to sign an assent form (your parent/ guardian will also sign a consent form). You will have some tests to make sure that the study is safe for you. They are very similar to tests that you would have done at your regular hospital visit. If you are eligible then you will be given secukinumab or adalimumab and methotrexate or mycophenolate mofetil to take together to see if they help make your eyes better.



You will be asked to come into the hospital up to 11 times over 2 years so the study staff can see how you are getting on with your new medicine. At these visits the study staff will carry out some assessments/ procedures that you are familiar with, described below. There might be some extra visits as part of the study and your doctor or research nurse will explain these to you. Not all the tests will be done at every visit.

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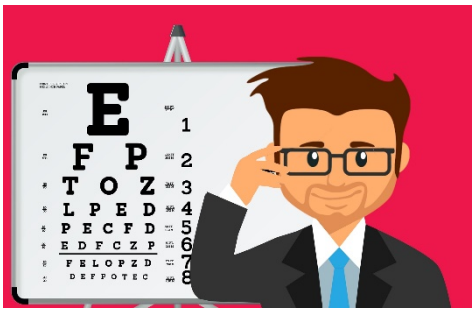
- Answer questions - you will be asked questions about how you feel. Please tell your doctor or nurse if you have felt unwell after taking your medicine.
- Eye tests - you will be asked to do some tests to check your eyes. One of these tests is called an Optical Coherence Tomography (OCT) scan. This is quick and safe and gives us a good picture of your eye. The doctor will also look at the rest of your body to check everything is ok



- You will be weighed, your height measured and your temperature checked. You will have a band put around your arm to measure the blood flowing through it (blood pressure). Your physical development will also be assessed.
- Skin test - you will have an injection into your skin to test for a disease called tuberculosis that you may have had in the past. If this test is positive, then you will need to have a chest X-ray. Your doctor or nurse will explain to you how this works.
- Blood tests and urine - you will have some blood and urine collected. We will take around 2 teaspoons (10mls) of blood for the routine tests.

Extra tests / procedures that carried out as part of the study

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- Questionnaires- you will help your parents or guardians answer some questions on how you are feeling.
- Treatment Diary - you will be asked to keep a record of the medicines you take in a diary; this also includes the study medicine. The study doctor or nurse will explain to you how to fill this in. This diary will be used to see what medicines you have been taking and when you are taking them.
- Study medicine - you will be given the new medicine (secukinumab) or you may be given a medicine called adalimumab. These medicines will be given by injection. Your parents or guardians may be shown how to give you your medicine so that they can do it at home for you. If you feel happy and confident then you can also do it yourself.
- Give extra blood for research in the future. If you are happy to give blood then we will take about 1 teaspoon (5mls) or 4 teaspoons (20mls) of blood depending on how much you weigh.

What will I have to do?

- Keep your study appointments according to the study calendar.
- Tell the study doctor about any side effects, GP visits or visits and admissions to hospital.
- For girls only, tell the study doctor, a member of the study staff or your parents/guardians if you believe you are pregnant.
- Answer questions about your medicines or general health.
- Tell your study doctor or staff straight away if you feel unwell or have any symptoms that worry you.
- Tell the study staff about any other medicines that you take.

- Tell the study doctor or a member of the research study staff if you change your mind about continuing to take part in this study.

Are there any other medicines I can take?

Secukinumab and adalimumab are two of several treatments that may be used to try and control your symptoms of JIA- associated uveitis. Your doctor will discuss other treatment options with you if you do not want to take part in the study. Or you can choose to stay on the medicine that you are using now.

What are the possible side effects and risks of taking the medicine?

You may have a few unpleasant side effects (listed below) and your doctor will watch you closely to make sure you're ok whilst you are taking your medicine.

- Fever, flu-like symptoms, night sweats
- Feeling tired or short of breath, cough which will not go away
- Warm, red and painful skin, or a painful skin rash with blisters
- Burning sensation when passing urine
- Difficulty breathing or swallowing
- Low blood pressure, which can cause dizziness or light-headedness
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin, with a red rash or raised bumps
- Upper respiratory tract infections with symptoms such as sore throat and stuffy nose
- Cold sores
- Diarrhoea
- Runny nose
- Athlete's foot
- Headache
- Nausea
- Fatigue

Some tests that happen at the study visits will be tests that you're used to but they may cause you a little discomfort:

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- You will be asked to give some blood, which can make you feel a bit dizzy. Rarely, bruising, a small blood clot or infection could occur where the blood was taken. Your doctor or the research nurse may apply a topical anaesthetic (a cream that numbs your skin) to make it less painful.
- When you have had your blood pressure taken, the blood pressure cuff may feel a bit tight and you may have a small bruise on your arm.
- When you have a dose of your new medicine it will be injected just under the skin and may cause some pain, redness, bruising or itching.
- The Purified Protein Derivative (PPD) test to check for tuberculosis may cause some swelling and hardness at the injection site.
- If you have to stop certain medication to be allowed to enter the trial then your disease may temporarily become worse.

What are the possible benefits of taking part in the study?

Taking the new medicine may make you feel better or it could make you feel worse, we can't be sure. By taking part you are helping doctors understand your disease and this may help other children with your disease get better in the future.

What happens at the end of the study?

There is no guarantee that the drug will be available to you at the end of the study. Your doctor will talk to you about this near the end of the study.

What if new information becomes available during the study?

Sometimes during a study, new information becomes available. If this happens the study doctor will tell you and your parents/guardians about it and will help you decide whether you want to carry on in the study. If you decide to withdraw or the study stops for another reason your doctor will arrange for your care to continue.

What happens if there is a problem?

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If there is anything about the study that is worrying you or you aren't happy please talk to your doctor or parents or guardians about it.

If you want leave the study at any time for any reason you can and no one will mind. Your doctor may also take you out of the study at any time if they think it would be better for you to take other medicine.

Will my taking part in the study be kept private?

With your agreement and your parents' / guardians' permission we will let your GP know that you are taking part. Some named information about you is sent to the main study office in Liverpool, but they will be very careful to keep this confidential. Some of your safety information will be sent to Novartis securely but we will not send them your name or other personal details. We will also send some of your data with any blood samples you give to the Bristol Biobank.

All data collected during the trial will be kept for a maximum of 25 years after the trial has ended. During this time all of your information will be kept confidential.

The collection and handling of your personal data will be managed in accordance with GDPR and the Data Protection Act. University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) and Liverpool Clinical Trials Centre (LCTC) are the Data Controllers for this study and will need to use information from your medical records for this research project.

Who is running this study?

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We have received money to run this study from Novartis. It is being managed by a Clinical Trials Unit in Liverpool called the Liverpool Clinical Trials Centre. The study is sponsored by University Hospitals Bristol and Weston NHS Foundation Trust. The University of Liverpool and University Hospitals Bristol and Weston NHS Foundation Trust are the data controllers for this study.

Before any study can begin it has to be checked by a group of people known as a Research Ethics Committee (and it is their job to check that the research is ok to do before anyone is asked to take part in a study.)

Contact details

Please contact your doctor on the telephone number given below if you have any more questions about the study or if there is anything you don't understand.

Local Investigator:

Research Nurse:

You can also find our more information on the study website – www.turtle-trial.org.uk

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11-15 Years Assent Form

To be completed by the Researcher:

Site Name:	
Participant Study Number	
Participant Initials:	Participant DOB: / /

To be completed by the Researcher:

Section 1 – Assessing Developmental Capacity		
Does the child have the developmental capability / mental capacity to consider assent? *If "YES", you should approach the child for assent - proceed to section 2.* *If "NO", you should <u>not</u> approach the child for assent – skip section 2, sign and date section 3 and return a copy to LCTC*	Yes ☐	No ☐
Section 2 – Approaching for Assent		
If approached for assent, did the child express to you that they <u>did NOT wish</u> to make a decision about assent? *If "YES", you should <u>not</u> approach the child for assent – sign and date section 3 and return a copy to LCTC* *If "NO", please sign and date section 3, then give this form to the child and the adult consenting on their behalf for completion.*	Yes ☐	No ☐
Section 3 - Signature		
Name and Role:		
Signature and Date:		

Young person to circle all they agree with:

Have you read (or had read to you) information about this study?	Yes / No
Has somebody else explained this project to you?	Yes / No
Do you understand what this study is about?	Yes / No
Have you asked 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 be part of this study?	Yes / No
Do you understand that your parents or guardians have agreed to you taking part in this study?	Yes / No

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11-15 Years Assent Form

To be completed by the Researcher:																	
Site Name:																	
Participant Study Number																	
Participant Initials:				Participant DOB:			/			/							

If any answers are "no" or you don't want to take part, don't write your name!

If you do want to take part, please write your name and today's date.

Your Name: _____

Date: _____

Your parent / guardian must write their name here too if they are happy for you to take part in the study.

Name of parent / guardian: _____

Signature: _____

Date: _____

The researcher who explained this study needs to sign too:

Name of Researcher: _____

Signature: _____

Date: _____

Please file the original wet-ink copy in the TURTLE Investigator Site File, and make three copies: one for the participant, one for the medical notes and one to be sent to the LCTC.