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The Acne-ID study

Investigating the benefits and harms of reduced daily dose oral isotretinoin in the treatment of acne

Information Sheet for young people aged 12 – 15 years

We are researchers at the University of Nottingham, and we would like to invite you to take part in one of our clinical studies called Acne-ID. Please read this information carefully and discuss it with a parent, or guardian, to decide whether you would like to take part. If there is anything that is not clear, or you would like more information, please ask your doctor or nurse.

1. What is the study and why is it important?

Around 1 in 10 people get severe acne that can scar their skin. Having acne on your face and body as a young person can affect your confidence, sometimes leading to low mood and anxiety. However, there is a very effective treatment for severe acne called isotretinoin.

Although isotretinoin works well at clearing acne at this dose, nearly everyone (8 in 10) experience side effects such as severe drying of the lips, skin and lining of the nose. Other side effects can occur including aching muscles and tiredness (2 in 10) and acne flares when starting treatment (2 in 10).

One way to reduce these side effects is to give a lower dose of isotretinoin, possibly over a longer period of time. But we want to be sure a lower dose for longer clears acne as effectively as the standard dose, and if people are happy to take the tablets for a longer time. It is also possible that if the acne is not fully treated at a lower dose, it will come back soon after stopping treatment. At the moment, doctors are not certain if a lower dose of this medicine is as effective as the standard dose at clearing acne.

This study will compare the advantages and disadvantages of the two different doses of isotretinoin for young people with severe acne – a lower dose possibly taken for a longer time, or a dose usually prescribed (standard care) for a shorter time. We will also be looking at side effects, how severe your acne is, satisfaction with treatment, and mood monitoring, during the study - to see which dose is most effective.

2. Why have I been invited to take part?

You have been invited to take part because your doctor has tried other treatments which did not help clear your acne, and you have both agreed to try isotretinoin.

3. Do I have to take part?

No, you can decide whether or not to take part in this study.

If you decide to take part now but change your mind later, that is fine too. You can stop taking part at any time, and it won't change how the doctor takes care of you now or in the future.

4. What does taking part in the trial involve?

If you are suitable to take part in the study, with your consent, you will be asked to take a photograph of your acne using your own phone or digital camera. This photograph is for your personal use only to help you best answer questions about changes in your acne and track treatment progress. You will not be asked to share the photograph with the trial staff or upload it anywhere.

If you do decide to take part, we'll put you into one of two groups: one taking a low dose of the medicine and the other taking the usual amount.

Group A: will take **a standard dose of medicine**
Group B: will take **a lower dose of medicine**

This is decided by a computer using a process called 'randomisation', neither you nor your doctor will be able to choose which group to be in. This ensures that the comparison is fair and balanced. You or your parent/carer won't know which group you're in, and neither will your dermatology team. This is so you can answer questions about your treatment honestly.

Both groups will take the medicine every day for up to 12 months or until your acne clears, or you stop taking isotretinoin whichever happens first. We suggest taking your medicine at the same time every day with food that has some fat in it. This helps your body absorb the medicine better. For example, you could take it with toast and butter, or with a glass of milk.

If you have any questions about any of this, just ask. We're here to help you understand everything.

Whilst on isotretinoin:

Whilst taking your medicine, you will have regular visits with the dermatology team every 2 months and at end of your treatment. During these visits, someone who doesn't usually treat you will check your acne, and they won't know if you're taking a high or low dose of isotretinoin. It's important not to talk to them about your treatment, as it could affect the study's results.

We will send you some questionnaires to complete (via email or post your choice), your parent/carer will get reminders to help you both to remember what needs to be completed and when.

Anyone who may be able to get pregnant whilst taking isotretinoin must enter the Pregnancy Prevention Programme. If relevant to you, your doctor will ask you to sign a form to ensure that you are aware of the risks to an unborn baby.

Your doctor will only let you start taking isotretinoin if you are not pregnant, this will be confirmed by a routine pregnancy test in clinic. As it is important not to become pregnant whilst taking isotretinoin, testing throughout the treatment period will vary dependent on risk.

Those who are sexually active must use highly effective contraception (the coil (IUD), intra-uterine system (IUS), or contraceptive implant which has been in place for at least 4 weeks) or two forms of contraception together (the hormonal contraceptive pill or contraceptive injection plus a barrier method, such as a condom) and continue to use this method throughout the treatment period and for 1 month after.

After treatment:
Once you have finished taking the medication (up to 12 months), we will then send you questionnaires for another 12 months to see how you are getting on. You can choose to fill them out online or on paper. If you choose online, we'll send you and/or your parent/carer, automated texts and emails with questionnaire link and reminders. If you prefer paper, we'll post the questionnaires to your house with a prepaid envelope for you or your parent to send back. It's an easy way to let us know how you're feeling after the treatment. If we don't get the questionnaires, someone from our research team might give you or your parent/carer a call to check in.

Optional studies
At the start of the study, we'll ask if you're okay with being interviewed about your experience of acne and isotretinoin. About 30 people who agree will be invited for a chat, either in person, online, or on the phone, to share their thoughts. This helps us understand how the treatment works for different people. If you're interested, we'll give you more information and a form to fill out.

Also, if you're curious about how isotretinoin works in the body, you can choose to be part of another study. The separate study using the blood samples and skin swabs will aim to find out more about how well isotretinoin works and the development of side effects. It will also aim to find out how the skin and hair, which includes the bacteria on the skin, is affected by taking isotretinoin. An additional blood sample will be stored and used for any future related studies coordinated by the study team to understand the effects of isotretinoin.

The blood samples taken (5-9mls, approximately 1-2 teaspoons full) will be sent by the hospital to the University of York who will store the samples and conduct the research. Samples will be labelled using your participation identification number and date the sample was taken. Therefore, any third parties accessing samples will not have access to identifying information. As this is a separate study, the results will not be shared with participants. After the study has been completed, all your samples will be destroyed in line with HTA requirements.

Blood and urine samples for pregnancy testing and other safety monitoring, may be taken and reviewed by your usual dermatology team. These samples are not for the Acne-ID trial.

5. What will happen if I don't want to carry on with the study?

If you change your mind at any time and don't want to carry on in the study, that is okay. Taking part in this study is your decision.

If you are unsure at any stage, then please speak to your parent/carer about how you are feeling. You can also tell someone in the Acne-ID research team.

6. What are the possible benefits?

We do not know the benefits and harms of a reduced dose of isotretinoin in treating acne and that is what you will help us to find out. This study may not directly help you, but the information we collect may help other doctor and patients make decisions in the future.

7. What are the possible disadvantages and risks?

If you're in the low dose group, you might need to take isotretinoin for a bit longer than if you were in the standard dose group, probably between 6 and 12 months. But don't worry, during this time, all the usual check-ups and monitoring will still happen to make sure you're doing okay.

There is a small chance that you may get unwanted side effects from the medicine that you are taking, no matter if you are in low dose group or standard dose.

Some of the most known side effects are:

- Acne getting worse
- Dry lips, skin eyes, nose or nosebleeds
- Sensitivity to the sun or sunburn
- Achy muscles and joints
- Low or changes in mood
- Changes in sexual function
- Headaches
- Problems with eye sight
- Hair thinning
- Feeling sick, diarrhoea or blood in your poo

Isotretinoin can also harm an unborn child which is why strict contraception (methods to prevent pregnancy) is needed during treatment.

If you have any questions or feel upset about taking part, you should speak to your parent/carer.

8. How will information about me be used?

The research sponsor (University of Nottingham), researchers at the Nottingham Clinical Trials Unit (part of the University of Nottingham) and the local site research team at <insert site name> will need to use information from you, your medical records and potentially your GP for this research project. This information may include your initials, NHS number, name and contact details. The researchers will use this information to do the research or to check your records to make sure that the research is being done properly. For example, they may gather information from your medical notes if you are not able to attend a visit.

People who do not need to know who you are will not be able to see your name or contact details; your data will have a code number instead. All information about you will be kept safe and secure. However, the anonymised information collected about you may be used to support other research in the future and may be shared with other researchers.

Once the trial has finished, some of the data will be kept so the results can be checked and you can be told what happened in the trial (unless you tell us you do not want to know). Reports will be written in a way so that no-one can work out that you took part in the trial.

Use the QR code below will to find out more information about how health researchers use information from patients.

9. What are my choices about how my information will be used?

We need to manage your research 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. After 7 years your data collected during the trial will be disposed of securely.

If you give us your permission, we may keep your contact details so we can get in touch if there is any relevant future research to do with acne treatment that you may be interested taking part in. 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.

With permission, you will also have the option to take part in future research using their data saved from this trial. If you do not wish for your contact details to be kept for a copy of the trial results to be sent to you or to be contacted about future research, these will also be disposed of securely at the end of the trial.

10. Where can I find out more about how my information will be used?

You can find out more about how we use your information:
- at www.hra.nhs.uk/information-about-patients/ and www.hra.nhs.uk/patientdataandresearch
- at https://www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx
- http://www.nctu.ac.uk/data-protection/data-protection.aspx
- by sending an email to the Data Protection Officer at dpo@nottingham.ac.uk
- by asking one of the research team
- by sending an email to acne-id@nottingham.ac.uk

11. Who is conducting the research?

The study is done by researchers that are experts in skin conditions. They are based at the Nottingham Clinical Trials Unit which is part of the University of Nottingham.

In the event that something does go wrong, and you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation, but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

12. Did anyone else check the study is OK to do?

The study has been reviewed by the Sponsor, University of Nottingham, and by the Research Ethics Committee. They make sure that everything we do is suitable for children and adults. The University of Nottingham also arranges insurance for this study.

13. What happens at the end of the study?

When the trial ends, your healthcare will continue as normal. At the end of the trial the results will be published in scientific medical journals and presented at conferences. You will not be identified in any publication. We will send you a newsletter with a summary of the trial findings unless you ask us not to.

14. How can I find out about this study?

Your parents or guardians who care for you have more detailed information and can answer your questions. Or you can ask us <insert local team contact>

15. How to contact us:

<insert local team contact details>

<insert local team contact details>

Acne-ID trial team email - acne-id@nottingham.ac.uk

Acne-ID trial website - www.acne-id.ac.uk

Thank you for taking the time to read this information sheet, if you have any questions please ask your doctor or parent/carer.