The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

DIPSoC
Developing Diagnostic criteria
for Psoriasis in Children

Local trust logo

A study to develop Diagnostic criteria for Psoriasis in Children and young people

An information sheet for parents and guardians

An invitation for your child to take part in our research study

- It is important you understand why the research is being done, and what it will involve.

- If you have any questions about this information or the study, please talk to the dermatologist or the research team.

- It is up to you and your child whether they take part. If you choose not to take part, this won't change anything about the quality of care your child receives or will receive in the future.

- Thank you for reading this information.

A quick summary of what you need to know

- We want to improve the diagnosis of psoriasis in children and young people by developing diagnostic criteria.

- Diagnostic criteria are a list of special skin changes or questions a doctors or nurse may ask when making a diagnosis. Our study will test how well the diagnostic criteria work at diagnosing psoriasis.

- In the study we would like to ask you and your child some questions. After this we would like have a look at your child's skin on different parts of the body. We only need to do this once and it will take about 30 minutes. **It is important you don't tell us the name of your child's skin disease.**

- There are no tests or medications in this study. If it is OK with you and your child we would like to use photographs already taken clinic as part of the research study.

If you have any questions about the study please see the end of this information sheet for contact details.

Contents

1. Why is this study important?

Psoriasis (pronounced sor-aye-asis) can cause skin changes anywhere on the body. For many people it can be a long-term condition and have a significant impact on their quality of life. Psoriasis can be associated with other diseases such as arthritis, which causes swelling and damage to the joints. It is therefore important that psoriasis is diagnosed early and accurately. For people with psoriasis, early diagnosis will help them receive psoriasis specific treatment.

Psoriasis in children and young people (17 years or younger) can be more difficult for doctors and nurses to recognise. This is because the appearance of psoriasis is often different in children compared to adults. Health professionals are also less familiar with psoriasis as a diagnosis in children. Developing diagnostic criteria (a list of skin changes and questions to ask when making a diagnosis of psoriasis) will help doctors and nurses to recognise psoriasis, even if they don't work in dermatology departments.

2. What are the aims of the study?

Our study aims to test how well each item on the list of diagnostic criteria work at diagnosing psoriasis. This list has been created with experts in psoriasis from around the world (through the International Psoriasis Council). Using the results from the study we will create an improved list of diagnostic criteria that best predict psoriasis.

We will test the criteria by inviting children/young people with psoriasis and children/young people with other skin conditions to take part. We will investigate how well the diagnostic criteria separate those with psoriasis from those with another skin condition.

3. Who is leading this research and has it been approved?

The study is being led by a researcher, Professor Kim Thomas, and a dermatology (skin) doctor, Dr Esther Burden-Teh, from the University of Nottingham. This is a combined project with doctors and nurses in the NHS, researchers from Universities of Nottingham and Rotterdam, and people with psoriasis. The research is funded through the National Institute for Health Research, the research part of the NHS.

This study has been reviewed and approved by the Research Ethics Committee (REC). The REC looks after the rights, wellbeing and dignity of people invited to take part in research studies. The study has also been reviewed by children, young people and adults with psoriasis.

4. Why has my child been invited to take part?

To help us answer our research question we are inviting about 320 children/young people to take part. We will invite people with psoriasis and people with other skin diseases, including your child, to help with the study.

5. Does my child have to take part?

It is up to you and your child to decide whether or not to take part. If your child takes part you will be given this information sheet to keep and be asked to sign a consent form. If your child takes part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

6. What will we have to do if my child takes part and how long will it take?

If you and your child decide to take part in the study you will meet a member of the research team on one occasion. **It is very important that you don't tell the researcher the name of your child's skin disease.**

At the visit we will ask you and your child some questions. We will then look at your child's skin in many different places. Some of the places we will want to look are in their hair, on their stomach, in their umbilicus (belly-button) and flexures (armpits and groin). A family member or a nurse/doctor can be present during the skin examination. For children/young people aged 4 to 17 years, we will also give your child or you to complete on their behalf a quick questionnaire to complete about how their skin disease affects them.

The assessment will be completed in a sensitive manner and will maintain your child's privacy. Your child could wear a hospital gown if they would like to.

Inside this main study, we will also perform a number of important checks. We will check for the consistency of the diagnostic criteria assessment, the consistency of the psoriasis diagnosis and how well the criteria perform on children who might have psoriasis. For these 'mini-studies' the following may happen in some children. In a small number of children two researchers will do the diagnostic criteria assessment one after the other. We may also like to include some photos of your child's rash (which have been taken as part of their usual care) in the study, but only if it is OK with you and your child. Please ask if you would like to see the photos we wish to include. We will also send some children/young people a questionnaire after the main study has closed to find out what has happened to their skin disease.

For our study we only need to see your child on this one occasion. The visit will take about 30 minutes.

7. Are there possible disadvantages?

The study does not involve any tests or medications. We will need to look at their skin in more private body sites such as their groin. The study does not change their individual medical treatment and will not improve their skin disease.

8. Are there possible benefits?

The results from the study will hopefully help children and young people in the future to be diagnosed with psoriasis earlier and more accurately. Every child/young person who takes part will receive a certificate/sticker and a gift voucher to say thank you.

Read on to find out more details about the study and what to do if there is a problem.

9. Will my child's information be kept confidential?

We will use ethical and legal guidelines to make sure we handle all information about your child in confidence (not sharing it with anyone who isn't working on the study or who you haven't given us permission to share it with). If you join the study, some parts of your child's medical records and the data collected for the study will be looked at by the research team at the University of Nottingham. Anyone who sees your data will be required to keep everything they see confidential and respect your right to privacy.

All information which is collected about your child during the course of the research will be kept strictly confidential, stored in a secure and locked office, and on a password protected database. Any data about your child which leaves the hospital will have their name removed (anonymised) and a unique code will be used instead so that your child cannot be recognised.

All research data will be kept securely for 7 years. After this time your child's data will be disposed of securely. During this time, everyone involved in the study will make sure that your child's right to privacy is protected. Anonymised data may be used to support research in the future and shared with other researchers.

If you and your child agree to it on the consent form, your child's contact details will also be kept securely at the Centre of Evidence Based Dermatology after the end of the study so we are able to contact them about the results of the study, what has happened to their skin disease and future related studies. If you don't want your child's contact details to be kept and used in this way, or if in the future you decide you no longer want us to hold your personal details that is fine. You can let us know and we will remove your child's details from our database.

10. Will I find out the results of the study?

The results from this study will be published in medical journals, presented at medical conferences and shared with patient groups and relevant charities. We will send you and your child a newsletter with a summary of the study findings, unless you ask us not to.

11. What if there is a problem?

If you have a concern or questions about any part of this study, you can speak to your research team or dermatologist working on the study (their contact details are on the front page of this leaflet).

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure by emailing england.contactus@nhs.net (ensuring you state 'For the attention of the complaints manager' in the subject line) or via the Local Patient Advisory and Liaison Service (PALS).

Contact details

Local contact details:

Central contact details:

Email address: dipsoc@nottingham.ac.uk

Postal address: Centre of Evidence Based Dermatology, Kings Meadow Campus, University of Nottingham, Nottingham, NG7 2NR

Research leads

Dr Esther Burden-Teh

Study Coordinator

Centre of Evidence Based Dermatology

University of Nottingham

Prof Kim Thomas

Chief Investigator

Centre of Evidence Based Dermatology

University of Nottingham

Dr Esther Burden-Teh is funded by a National Institute for Health Research Doctoral Research Fellowship DRF-2016-09-083