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Developing diagnostic criteria for psoriasis in children

Submission date	Recruitment status
24/10/2017	No longer recruiting
Registration date	**Overall study status**
07/11/2017	Completed
Last Edited	**Condition category**
30/12/2021	Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Psoriasis is a skin condition that can cause red, flaky patches on any part of the body including the face, scalp, hands and genitals. Children and young people with psoriasis can develop an inflammatory arthritis leading to swelling, discomfort and permanent joint damage. Psoriasis may also lead to obesity and long-term health problems such as high blood pressure and diabetes. It is therefore important that psoriasis is diagnosed accurately and early, so that specific treatment and monitoring can be started. Psoriasis is often difficult to diagnose in children and young people. Research shows that up to nine in ten children with psoriasis are mistakenly diagnosed with other skin conditions by non-dermatologists. A group of experts in psoriasis from around the world have agreed a list of diagnostic criteria that are important for the diagnosis of psoriasis in children/young people. In this study, the agreed diagnostic criteria are tested in children/young people with psoriasis and children/young people with other skin conditions. This study assesses how well the criteria separate these two groups. The results are used to improve the diagnostic criteria by removing those that poorly predicted psoriasis.

Who can participate?
Children/young people, aged 0 to 18 with possible or confirmed psoriasis or a scaly inflammatory rash

What does the study involve?
Participants attend for one study visit lasting about 30 minutes. All participants undergo an assessment based on the 16 items agreed as important for the diagnosis of children and young people. The assessment includes a physical examination and clinical questioning. Demographic information and quality of life data are also collected. The assessment is undertaken by a trained research nurse or study investigator and the assessor, where possible, is unaware of the child's /young person's diagnosis. The first 40 participants recruited are assessed by two different assessors one after the other to test the variability of the diagnostic criteria. Additional information are collected from participants' medical records, including the confirmed dermatologist's diagnosis, disease severity, duration of disease, and current skin medications.

What are the possible benefits and risks of participating?
The study does not involve any tests or medications, and will hopefully help children and young

people to be diagnosed with psoriasis earlier and more accurately in the future. Participants in the study will have their skin closely looked at, including more private body areas such as the groin and bottom. The study does not change their individual medical treatment and will not improve their skin disease.

Where is the study run from?
The study takes place at children's' dermatology departments across the UK and is led from the University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
August 2016 to August 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Esther Burden-Teh
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
220116

Study information

Scientific Title
Developing diagnostic criteria for psoriasis in children and young people: a multi-centre case control study in paediatric dermatology clinics

Acronym
DIPSOC

Study objectives
The best predictive diagnostic criteria can be developed from the consensus agreed diagnostic criteria using a multivariate model and will achieve a sensitivity and specificity of >70% with the fewest number of essential items.

The benefit of developing diagnostic criteria for psoriasis in children will be to improve diagnosis by non-dermatologists such as GPs and paediatric rheumatologists. This will ensure children are referred to secondary care, receive psoriasis specific treatment and undergo monitoring for associated diseases (eg juvenile psoriatic arthritis) as per national guidelines (NICE 2012). Diagnostic criteria will also standardise disease definitions in studies; improving quality and permitting meta-analysis. This study will also investigate the performance of the diagnostic criteria in indeterminate psoriasis; providing preliminary information on whether the diagnostic criteria can help predict psoriasis in those with possible psoriasis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Nottingham 2 Research Ethics Committee, 03/02/2017, ref: 17/EM/0035

Study design
Multi-centre case-control diagnostic accuracy study with a nested sub-study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Psoriasis in children and young people

Interventions
All participants to undergo a diagnostic criteria assessment based on the 16 diagnostic items that the consensus study agreed as important for the diagnosis of children and young people. The assessment includes a physical examination and clinical questioning. Demographic information and quality of life data will also be collected. The assessment will be undertaken by a trained research nurse or study investigator and the assessor, where possible, will be unaware of the child's/young person's diagnosis. The first 40 participants recruited will be assessed by two different assessors consecutively to enable inter-observer variability of the diagnostic criteria to be evaluated. Additional information will be collected from the medical record. These data will include the confirmed dermatologist's diagnosis (reference standard), disease severity, duration of disease, and current skin medications.

Intervention Type
Not Specified

Primary outcome(s)
Consensus agreed diagnostic criteria vs reference standard (dermatologist's diagnosis). The presence or absence (binary) of each of the diagnostic criterion will be assessed by study investigators trained to undertake the diagnostic criteria assessment and blinded to the diagnosis of the participant. The threshold for diagnosis according to the consensus agreed diagnostic criteria has been determined through the consensus study. The diagnostic accuracy of the consensus agreed diagnostic criteria will be assessed using sensitivity and specificity. The best predictive diagnostic criteria will be developed using multivariate analysis and the decision to include individual criteria in the model will be based on the likelihood ratio.

Key secondary outcome(s))
1. The diagnostic performance of the consensus agreed diagnostic criteria and the best predictive criteria for plaque psoriasis (measured as per the primary objective); these criteria will be graphically presented and compared on Receiver Operator Characteristic (ROC) curves
2. The inter-observer variability in the diagnostic criteria assessment; two study investigators will independently undertake the diagnostic criteria assessment. The variability between the investigators will be assessed using the Kappa statistic
3. The variability in the reference standard for psoriasis; a sample of clinical images of participants with psoriasis (taken as part of routine practice) will be anonymised and circulated amongst clinical principal investigators. The variability in principal investigators' opinions on the diagnosis of psoriasis will be assessed using the Kappa statistic
4. The performance of the best predictive diagnostic criteria in identifying children/young people with psoriasis currently diagnosed with indeterminate disease (nested sub-study); a questionnaire will be sent 24 months after the end of the study asking about their current skin disease. The best predictive criteria vs participant reported diagnosis from the questionnaire. The performance of the best predictive criteria will be assessed using sensitivity and specificity

Completion date
31/08/2019

Eligibility

Key inclusion criteria
Cases:
1. Children/young people (0 to <18 years of age)
2. Confirmed diagnosis of plaque psoriasis by a dermatologist
3. Active disease at the time of assessment
4. Able to consent

Controls:
1. Children/young people (0 to <18 years of age)
2. Confirmed diagnosis of a scaly inflammatory rash (excluding psoriasis and indeterminate psoriasis) by a dermatologist
3. Active disease at the time of assessment
4. Able to consent

Indeterminate psoriasis:
1. Children/young people (0 to <18 years of age)
2. Diagnosis of indeterminate or possible psoriasis by a dermatologist
3. Active disease at the time of assessment
4. Able to consent and willing to receive a follow-up questionnaire after 24 months

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Child

Upper age limit
18 years

Sex
All

Total final enrolment
348

Key exclusion criteria
1. Children/young people with pustular psoriasis
2. Children/young people with erythrodermic psoriasis
3. Children/young people without a dermatologist's diagnosis

Date of first enrolment
25/10/2017

Date of final enrolment
29/03/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust
Queens Medical Centre
Derby Road
Nottingham
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 08/03/2021:
The datasets generated during and/or analysed during the current study will be stored in Nottingham Research Data Management Repository (researchdata@nottingham.ac.uk)
Type of data that will be shared: Excel workbook (.xlsx) comma-delimited (.csv) file of raw data with data dictionary
When data will become available and for how long: Data will become available after publication and will be available for 7 years
Access criteria: The researchers request that all researchers interested in using the DIPSOC study data to contact the Chief Investigator. Studies using the data for secondary analyses will be required to have obtained the necessary ethical approvals which will depend on their institution and local requirements.
Was consent obtained: Consent was obtained from participants at entry into the study for data to be shared anonymously with other researchers

Comments on data anonymisation: Data has been anonymised by removal of all participant identifiable information

Previous IPD sharing statement
Anonymised participant-level data will be made available on request. The data will be held at the University of Nottingham.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/09/2021	30/12/2021	Yes	No
Protocol article	protocol	27/08/2019	02/09/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes