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# The UK-Irish Eczema Register

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 11/07/2018 | Recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 21/01/2019 | Ongoing | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 14/12/2023 | Skin and Connective Tissue Diseases | [_] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Eczema (or dermatitis) is a dry skin condition that can affect people in different forms. It can lead to constant scratching, which causes the skin to split and bleed, and leaves it open to infection.
Eczema can be treated using “systemic immuno-modulators”. People with eczema have an overactive immune system that is inflamed. Immuno-modulators are used to suppress the immune system, which in turn reduces inflammation. As they are systemic, they affect the entire body, rather than just one specific area.
Since eczema is a long-term condition, it is important to understand how well such treatments work in terms of improvement in disease control, quality of life and safety over long periods of time. These treatments have undergone careful clinical trials, but the picture we get from clinical trials is not complete. This project aims to fill the gap in knowledge and collect information from patients using systemic immuno-modulators who attend regular dermatology clinics, to better understand the “real world” use of these medicines. It aims to look at side effects, especially for patients taking medication for other conditions, to increase understanding of the risk of using these therapies. It will also look at the "real cost" of these eczema treatments, to examine how much the therapies cost in the long term compared to how well they work.

Who can participate?
Patients with atopic eczema who are about to start a systemic immuno-modulator therapy.

What does the study involve?
Participants will be asked to complete questionnaires in addition to their usual clinic assessments. They will also be asked to donate an optional DNA sample. The study intends to set up a biorepository, which is where patients will be asked to provide optional blood and skin samples to help us better understand how eczema develops and why therapies work better for some people than others, or cause more side effects in others. Donation to the biorepository is a completely optional section of the study.

What are the possible benefits and risks of participating?
There are no additional clinical benefits to participants other than that the information obtained will help the dermatology community better understand the disease and develop more effective treatments in future. There are no known risks to participants taking part in the questionnaire

section of the study. For the blood sample collection, the risks may be discomfort and potential bleeding or bruising. For the skin biopsy, the risks include discomfort, infection, scarring, a reaction to local anaesthetic or bleeding.

Where is the study run from?
The study is run from King's College London and Guy's and St Thomas' NHS Foundation Trust. 13 centres across the UK and 1 in Ireland will be open to recruitment in the initial stage of this study, which may later expand. Guy's an St Thomas' NHS Foundation Trust is the lead centre.

When is the study starting and how long is it expected to run for?
July 2017 to December 2026

Who is funding the study?
The British Skin Foundation (UK)

Who is the main contact?
1. Carsten Flohr (carsten.flohr@kcl.ac.uk)
2. Sonia Serrano (sonia.serrano@gstt.nhs.uk)

### Study website
http://astar-register.org

## Contact information

### Type(s)
Public

### Contact name
Mr Prakash Patel

### Contact details
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### Type(s)
Scientific

### Contact name
Prof Carsten Flohr

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SE17EH

## Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
237309

## Study information

### Scientific Title
The UK-Irish Atopic Eczema Systemic Therapy Register

### Acronym
A-STAR

### Study objectives
To establish the short- and long-term effectiveness of systemic immune-modulatory therapies in adults and children with atopic eczema

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Wales Research Ethics Committee 1, final ethical approval expected by 08/08/18, IRAS ID: 237309, REC ref. 18/WA/0200

### Study design
Observational prospective multi-centre cohort clinical registry

### Primary study design
Observational

### Secondary study design
Cohort study

### Study setting(s)
Hospital

## Study type(s)
Other

## Participant information sheet
http://astar-register.org/participants

## Health condition(s) or problem(s) studied
Atopic Eczema

## Interventions
During the observation period, participants will be assessed on a regular (3-6 monthly basis) to collect data on disease severity and other clinical outcomes (such as quality of life), adverse events, reasons for potential changes in therapy and key healthcare resource use (e.g. hospitalisations, specialist and GP visits, and drug use). The latter will form part of the health economic feasibility assessment, which will also examine the potential use of HES and CPRD data for health economic evaluation purposes.
Participants will be involved in the study for as long as possible but for a minimum of 1 year. We have incorporated different types for study withdrawal for patients who may not want to attend study visits, but allow us to link their data with healthcare providers, so indirect participation may continue for a long period.

## Intervention Type
Other

## Primary outcome measure
Treatment effectiveness will be assessed at the baseline, after 4 weeks, 12 weeks, 6 months, 9 months, 12 months and every 3-6 months thereafter using the following:
1. Physician-assessed severity measures assessed through changes in the following at the baseline, after 4 weeks, 12 weeks, 6 months, 9 months, 12 months and every 3-6 months thereafter:
1.1. EASI (Eczema Area and Severity Index)
1.2. EASI-50
1.3. EASI-75
1.4. IGA (Investigator's Global Assessment)
2. Patient-reported severity measures, assessed through changes in the following at the baseline, 12 weeks and every 6 months thereafter:
2.1. POEM score (Patient Oriented Eczema Measure)
2.2. Quality of life (DLQI/CDLQI/IDQOL) (Dermatology/Children’s Dermatology Life Quality Index)/EQ-5D)
2.3. ACQ score (Asthma control Questionnaire) in patients with a diagnosis of eczema
3. Disease control, assessed as totally or well controlled weeks at the baseline, after 4 weeks, 12 weeks, 6 months, 9 months, 12 months and every 3-6 months thereafter
4. Drug survival and long-term control of disease (time to discontinuation of treatment), assessed using the Kaplan-Meier survival technique and Cox regression analysis.

## Secondary outcome measures
1. Pharmacovigilance/safety reporting: All (S)AEs will be recorded at the baseline, after 4 weeks, 12 weeks, 6 months, 9 months, 12 months and every 3-6 months thereafter. Long term linkage data will be used for this purpose as well.
2. Cost-effectiveness analysis: We will calculate the mean costs and assess generic quality of life with the EQ-5D, assessed at the baseline, after 12 weeks, 12 months and every 6 months after,

for each treatment group/pathway to inform the development of an economic model. This will be in adherence to NICE (2013) methods guidance – whose objective is to estimate (i) long-term cost and QALYs for each treatment options, and (ii) incremental cost-effectiveness estimates to assess the value for money of each intervention. Value of information analysis will be used to identify those areas for further research which have the highest return in terms of population health
3. Standardised biorepository: blood, leukocytes, serum, skin and swabs collected at the baseline, after 4 weeks, 12 weeks and 12 months.

### Overall study start date
13/07/2017

### Completion date
31/12/2026

## Eligibility

### Key inclusion criteria
1. Paediatric and adult patients with atopic eczema who due to the severity of their disease and /or impact on quality of life are commencing on or switching to another systemic immuno-modulatory agent (e.g. CyA, AZA, MTX or biologic treatments).
2. Written informed consent for study participation obtained from the patient or parents / legal guardian, with assent as appropriate by the patient, depending on the level of understanding.
3. Consent to participate in long-term follow up and access to all medical records, including hospital admission records and linkage to data held by NHS bodies or other national providers of healthcare data.
4. Diagnosis of atopic eczema in keeping with the UK/Irish diagnostic criteria.
5. Willingness to comply with all study requirements.
6. Competent use of English language, according to patient's age (capable of understanding patient questionnaires).

### Participant type(s)
Patient

### Age group
All

### Sex
Both

### Target number of participants
200

### Key exclusion criteria
1. Insufficient understanding of the study by the patient and/or parent/guardian.
2. Patients who are currently participating in a randomised clinical trial.

### Date of first enrolment
01/09/2018

**Date of final enrolment**
31/12/2025

# Locations

**Countries of recruitment**
England

Ireland

Scotland

United Kingdom

Wales

**Study participating centre**
**Guy's and St Thomas' NHS Foundation Trust**
Trust Offices
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

**Study participating centre**
**The Newcastle Upon Tyne Hospitals NHS Foundation Trust**
Freeman Hospital
Freeman Road
High Heaton
Newcastle
United Kingdom
NE7 7DN

**Study participating centre**
**University Hospital Southampton NHS Foundation Trust**
Mailpoint 18
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

**Study participating centre**
**Great Ormond Street Hospital for Children NHS Foundation Trust**
Great Ormond Street
London
United Kingdom
WC1N 3JH

**Study participating centre**
**Manchester University NHS Foundation Trust**
Corbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

**Study participating centre**
**Sheffield Teaching Hospitals NHS Foundation Trust**
Northern General Hospital
Herries Road
Sheffield South
United Kingdom
S5 7AU

**Study participating centre**
**Sheffield Children's NHS Foundation Trust**
Western Bank
Sheffield South
United Kingdom
S10 2TH

**Study participating centre**
**University Hospitals Bristol NHS Foundation Trust**
Marlborough Street
Bristol Avon
United Kingdom
BS1 3NU

**Study participating centre**
**Oxford University Hospitals NHS Foundation Trust**
John Radcliffe Hospital
Headley Way

Headington Oxford
United Kingdom
OX3 9DU

**Study participating centre**
**Royal Hospital for Children**
West Glasgow Ambulatory Care Hospital
Dalnair Street
Yorkhill
Glasgow
United Kingdom
G3 8SJ

**Study participating centre**
**University of Dundee**
Dundee
United Kingdom
DD1 4HN

**Study participating centre**
**University of Edinburgh**
Department of Dermatology
Lauriston Building
Lauriston Place
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United Kingdom
EH3 9HA

**Study participating centre**
**University Hospital of Wales**
Cardiff
United Kingdom
CF14 4XW

**Study participating centre**
**Trinity College Dublin**
Dublin
Ireland
8

# Sponsor information

**Organisation**
King's College London

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Room 5.31 James Clerk Maxwell Building
57 Waterloo Road
London
England
United Kingdom
SE1 8WA

**Sponsor type**
University/education

**Website**
https://www.kcl.ac.uk/

**Organisation**
Guy's and St Thomas' NHS Foundation Trust

**Sponsor details**
16th floor, Tower Wing, Great Maze Pond
London
England
United Kingdom
SE19RT

**Sponsor type**
Hospital/treatment centre

**Website**
https://www.guysandstthomas.nhs.uk/home.aspx

# Funder(s)

**Funder type**
Charity

**Funder Name**
British Skin Foundation

### Alternative Name(s)
BSF

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
United Kingdom

## Results and Publications

### Publication and dissemination plan
The study results will be published in peer-reviewed journals and presented at national and international meetings, as well as in the study website (http://astar-register.org). A publication policy will be drawn up in due course to adequately reflect individual collaborators contributions.

### Intention to publish date
31/12/2026

### Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |