

The UK-Irish Eczema Register

Submission date 11/07/2018	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
Registration date 21/01/2019	Overall study status Ongoing	<input type="checkbox"/> Protocol
Last Edited 14/12/2023	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 and 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

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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 immunomodulatory 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
Edinburgh
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

Sponsor details

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)

The British Skin Foundation, bsfcharity, 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