ISRCTN52892540 https://doi.org/10.1186/ISRCTN52892540

Trial of food allergy IgE tests for eczema relief

Submission date
15/12/2022

Recruitment status
Recruiting

Registration date
17/01/2023

Overall study status
Ongoing

Last Edited
11/08/2025

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Eczema is common in children and causes dry, itchy and inflamed skin. Symptoms tend to come and go, and there are many reasons why a worsening or “flare” of eczema can happen. Many parents wonder whether a food allergy might be a cause, however, there is currently no good research evidence to support this.
The TIGER study is designed to help doctors and parents understand whether making changes to the diet of children with eczema, based on the results of food allergy tests, improves eczema control or not. The foods we are looking at are cow’s milk, hen’s egg, wheat and soya. Previous research into any link between food allergy and eczema symptoms is limited. This study is needed to help parents and doctors in the future know what is the best thing to do.

Who can participate?
Children aged between 3 months and 2 years, diagnosed with eczema who have not had a previous food allergy test or had an immediate reaction to the study foods (cow’s milk, hen’s egg, wheat and soya)

What does the study involve?
To find out if food allergy testing can improve eczema control, two groups of children (with equal numbers in each group) will be compared. We aim to run the study in up to 123 GP practices in England. Children will attend a study appointment at their GP surgery (or a nearby GP surgery) at the start of the study. During this appointment, children will have a skin assessment, and their growth will be measured. They will also be allocated to one of the two study groups by a process called randomisation. This means that nobody involved (the participants, their GP or the study team) decides or can predict which group each child gets put into. One group of children will receive standard care from their GP plus our ‘Good eczema care’ leaflet. The other group will also receive the leaflet plus they will be given dietary advice to follow for four study foods (cow’s milk, hen’s egg, wheat and soya) based on results from their food allergy tests (skin prick tests). A few children from the dietary advice group may be asked to attend the hospital for a day to make sure that all study foods are safe to eat at home, this is called an Oral Food Challenge. All children in the study will be followed up for 9 months and parents will be asked to complete study questionnaires about their child’s eczema symptoms, treatment use and diet every month during this time. All children will have a follow-up appointment 6 months after their first study appointment, at a time and place of their convenience to re-assess their skin and growth.

What are the possible benefits and risks of participating?
Most people find it rewarding to take part in medical research and appreciate the additional contact with the research team. The findings from the study will help doctors and parents in the future to decide if food allergy testing should be recommended for children with eczema. If the participant is in the dietary advice group, the food allergy tests may provide reassurance or reveal undiagnosed problems. Dietary advice based on the skin prick test results may not make any difference to the participant's eczema. There is a very small chance that a child may have a reaction to either the skin prick test or the Oral Food Challenge. Usually, any reaction is localised and mild. The risk of a serious ("anaphylaxis") reaction to skin prick tests is estimated to be less than 1 in a million. In the unlikely event of an emergency, there will be medical help on hand. Study procedures will include questionnaires at each time point. This will require the participant's time, but no other inconvenience or risk is expected. The questionnaires have been reviewed by the study patient and public involvement (PPI) members to ensure they are acceptable to patients.

Where is the study run from?
The University of Bristol with the Bristol Trials Centre (BTC) at the University of Bristol responsible for managing the study (UK)

When is the study starting and how long is it expected to run for?
August 2022 to October 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (Project reference: NIHR133464)

Who is the main contact?
Prof Matthew Ridd, tiger-study@bristol.ac.uk

Study website
https://www.bristol.ac.uk/eczema-allergy-study

Contact information

Type(s)
Principal Investigator

Contact name
Prof Matthew Ridd

ORCID ID
https://orcid.org/0000-0002-7954-8823

Contact details
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS
+44 (0)117 4552352
m.ridd@bristol.ac.uk

Type(s)
Scientific

Contact name
Ms Dominika Corejova

ORCID ID
https://orcid.org/0009-0009-6359-2561

Contact details
Bristol Trials Centre
1-5 Whiteladies Road
Bristol
United Kingdom
BS8 1NU
+44 (0)117 455 3039
d.corejova@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
318832

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 54714, IRAS 318832

Study information

Scientific Title
Trial of food allergy IGe tests for Eczema Relief (TIGER): individually randomised controlled trial (with internal pilot and nested economic and process evaluations) comparing the effect of skin prick test-guided dietary advice with standard care on eczema control in children

Acronym
TIGER

Study objectives
Does dietary advice based on routine food allergy tests improve disease control compared with standard care in children with eczema?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/02/2023, North West - Greater Manchester Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048328, (0) 2071048131; gmcentral.rec@hra.nhs.uk); ref: 22/NW/0387

Study design
Pragmatic multicentre parallel-group individually randomized controlled superiority trial with internal pilot and nested economic and process evaluations

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Management of eczema in children aged between 3 months and 2 years

Interventions
Participants are randomised on a 1:1 basis using an online randomisation system.

Group 1 - Intervention. Participants are given skin prick test-guided dietary advice for four study foods (cow's milk, hen's egg, wheat and soya), plus a 'Good eczema care' leaflet. (For safety, some participants may also have an oral food challenge at their local allergy centre, to ensure that advice to include foods at home does not risk a sudden, IgE-mediated, potentially life-threatening reaction).

Group 2 - Comparator/standard care. Participants are given a 'Good eczema care' leaflet.

Intervention Type
Behavioural

Primary outcome measure
Eczema control measured using the caregiver-reported version of RECap for AtoPic eczema (RECAP) questionnaire collected four-weekly for 24 weeks

Secondary outcome measures
1. Eczema control measured using the caregiver-reported version of RECap for AtoPic eczema (RECAP) questionnaire at 28 weeks, 32 weeks and 36 weeks
2. Eczema symptoms measured using a Patient-Oriented Eczema Measure (POEM) questionnaire four-weekly for 36 weeks

3. Itch severity measured using Numerical Rating Scale Peak Pruritis during the last 24 hours (PP-NRS) questionnaire four-weekly for 36 weeks
4. Eczema severity measured using Global eczema severity score four-weekly for 36 weeks
5. Eczema signs measured using Eczema Area Severity Index (EASI) at baseline and 24 weeks
6. Child quality of life (disease-specific) measured using an Infant Dermatitis Quality of Life (IDQOL) questionnaire at baseline, 24 weeks and 36 weeks
7. Child quality of life (generic) measured using Child Health Utility 9D scale (CHU-9D) questionnaire at baseline, 12 weeks, 24 weeks and 36 weeks
8. Growth of children measured using calculation of head circumference, weight-for-age, stature-for-age, and weight-for-stature at baseline and 24 weeks
9. Parent quality of life measured using the EuroQol-5 Dimension (EQ-5D-5L) and EQ-VAS questionnaires at baseline, 12 weeks, 24 weeks and 36 weeks
10. Parent quality of life measured using the Care Related Quality of Life (CarerQol) questionnaire at baseline, 24 weeks and 36 weeks
11. Parental anxiety measured using a Generalised Anxiety Disorder 7 (GAD-7) questionnaire at baseline, 24 weeks and 36 weeks
12. Breastfeeding status of the mother measured using questions from the Infant Feeding Survey four-weekly for 36 weeks
13. Healthcare resource use measured using the Resource Use Measure (RUM, including ModRUM and bespoke questions) at 12 weeks, 24 weeks and 36 weeks
14. Ingestion of study foods measured using a bespoke questionnaire four-weekly for 36 weeks
15. Use of topical treatments for eczema measured using a bespoke questionnaire four-weekly for 36 weeks
16. Eczema/food allergy genes measured in an optional DNA saliva sample measured using LGC Genomics using KASP genotyping technology at baseline or 24 weeks
17. Adverse events (including the development of food allergy) measured using medical notes captured throughout the full duration of participation

Overall study start date
01/08/2022

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. Aged between 3 months and less than 2 years
2. Have eczema diagnosed by an appropriately qualified healthcare professional
3. Have mild, moderate or severe eczema (Patient Orientated Eczema Measure (POEM) score >2 within the previous 28 days)
4. Be accompanied by an adult who is able to give consent

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Months

Upper age limit
2 Years

Sex
Both

Target number of participants
493

Key exclusion criteria
1. Confirmed or probable* immediate (IgE-type) food allergy to the study foods
2. Previous skin prick test (SPT) or IgE blood test for the study foods
3. Another child in the household already taking part in the trial

* Parents who report symptoms, which in the opinion of the allergy panel/their GP, are suspicious of an immediate-type reaction.

Date of first enrolment
01/03/2023

Date of final enrolment
22/08/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR CRN: West of England
Whitefriars
Lewins Mead
Bristol
United Kingdom
BS1 2NT

Study participating centre
NIHR CRN: Wessex
Unit 7 Berrywood Business Village
Tollbar Way
Hedge End
Southampton
United Kingdom
SO30 2UN

Study participating centre
NIHR CRN: Greater Manchester
2nd Floor
Citylabs
Nelson Street
Manchester
United Kingdom
M13 9NQ

Study participating centre
NIHR CRN: Thames Valley and South Midlands
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

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

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road

Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
University of Bristol

Sponsor details
Research and Enterprise Division
Augustine's Courtyard
Orchard Lane
Bristol
England
United Kingdom
BS1 5DS
+44 (0)117 4553343
research-governance@bristol.ac.uk

Sponsor type
University/education

Website
http://www.bristol.ac.uk/red/research-governance/

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

Publication and dissemination plan
Working with public contributors, we will develop and maintain a user-friendly website to publicise progress, stories and blogs to generate interest in the study. Through these mechanisms, we will reach many of the clinical, academic and lay audiences who have an interest in the subject area. This will generate some pathways to impact at an early stage in the study.

In addition to our final monograph, we will publish the trial protocol and results in peer-reviewed journals and present them at local, national and international meetings. Publications resulting from the quantitative and qualitative components of the study will cross-reference each other and include a universal trial reference number so that the studies can be located more easily. We will of course feed the results back to participating GP surgeries and participants.

We will disseminate the study findings to the wider NHS audience, via the Academic Health Science Network (AHSN) (Network of Networks) and partner organisations such as Allergy UK, producing a range of tailored outputs that are appropriate for the end user (decision makers, patients, researchers and clinicians), for example, executive ("actionable") summaries. In addition, we will produce a short video presentation/animation for sharing on websites such as YouTube, continuing medical education websites and through local community organisations.

Intention to publish date
30/11/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored on the University Research Data Storage Facility (RDSF) and will be available upon request from the Chief Investigator, Prof Matthew Ridd (m.ridd@bristol.ac.uk, or appointed nominee). The type of data that will be shared is anonymous research data, which may include qualitative audio recordings and/or associated data such as anonymised transcripts. Consent will be obtained from all participants for anonymous data to be shared with other researchers.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Protocol file	version 5.0	23/08/2023	18/12/2023	No	No