ISRCTN15090567 https://doi.org/10.1186/ISRCTN15090567

Atopic dermatitis anti-IgE paediatric trial

Submission date 03/12/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/12/2014	**Overall study status** Completed	
Last Edited 26/10/2020	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
Up to 1 child in 5 has eczema. Many of these children are successfully treated by creams or medicines. However, a small number of these children have such severe eczema that the available medicines are unable to control it. Other children have side effects from the medication, so that they cannot continue to take it. The aim of this study is to see if a new medication, Xolair (also known as omalizumab or anti-IgE), can help children with severe eczema, who have not responded to other available treatments.

Who can participate?
Children aged 4-19 with severe eczema that is not controlled by available medications.

What does the study involve
Participants are randomly allocated into one of two groups. Those in group 1 receive Xolair for 6 months. Those in group 2 are given a placebo for 6 months. All participants are then monitored for a further 6 months after treatment.

What are the possible benefits and risks of participating?
Ultimately it is hoped that the treatments in this study will help children with eczema. However, there is no guarantee that a child's eczema will get better if they participate in the study. The information we get from this study may, however, help to find better treatments for children with severe eczema with fewer side effects. Participants have to make a number of visits to hospital for the treatment. They also undergo allergy tests and other tests.

Where is the study run from?
Evelina Children's Hospital, St Thomas' Hospital, London (UK)

When is the study starting and how long is it expected to run for?
November 2014 to July 2016

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

Who is the main contact?
Dr Susan Chan

Contact information

Type(s)
Scientific

Contact name
Dr Susan Chan

Contact details
Guy's and St. Thomas' NHS Foundation trust
St Thomas's Hospital
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02300701

Secondary identifying numbers
17968

Study information

Scientific Title
The role of anti-IgE (omalizumab) in the management of severe recalcitrant paediatric atopic eczema

Acronym
ADAPT

Study objectives
This research aims to establish the role of anti-IgE therapy in children with severe eczema

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Westminster, 07/07/2011, ref. 11/LO/0123

Study design
Randomised interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Children; Subtopic: Allergy, Infect &Immun; Disease: All Diseases; Topic: Dermatology; Subtopic: Dermatology; Disease: Dermatology

Interventions
Patients will receive anti-IgE/Xolair/omalizumab or placebo for 24 weeks, and will be followed up for a further 24 weeks. Dosage and frequency of treatment will be determined by the standard manufacturer’s dosing tables, and will be administered by subcutaneous injection.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Omalizumab

Primary outcome measure
Eczema severity; Timepoint(s): End of treatment

Secondary outcome measures
N/A

Overall study start date
20/11/2014

Completion date
01/07/2016

Eligibility

Key inclusion criteria

1. Children between the ages of 4-19 years at the time of enrolment into the trial
2. Severe eczema with
2.1. an objective SCORAD (a validated eczema severity score) of over 40
2.2. in a patient unresponsive to optimal topical therapy (potent topical steroids and topical calcineurin inhibitors)
2.3. in whom there is no impression of lack of compliance
2.4. with a (C)DLQI score of ≥10
2.5. and in whom active infection has been ruled out and/or adequately treated
3. Raised SpIgE (>0.35 IU/ml)or SPT (>3mm)to at least 1 food allergen or 1 aeroallergen AND/OR
4. Clinical impression that allergic exposures cause worsening eczema.
5. Total IgE level >300 kU/l.
6. Clinically proven IgE-mediated allergic disease including at least 1 of the following:
6.1. Immediate hypersensitivity to a food as proven by raised specific IgE (SpIgE) or skin prick test (SPT) greater than the 95% positive predictive value or ≥8mm, or a positive double blind placebo controlled food challenge,
6.2. Allergic rhinoconjunctivitis as defined by sensitisation to a respiratory allergen and clinical history of rhinoconjunctivitis symptoms when exposed to the relevant allergen
6.3. Allergic asthma: a history of cough, wheeze, or shortness of breath that
6.3.1. Was responsive to therapy with bronchodilators on two or more occasions in the previous 24 months
6.3.2. Required one visit to a physician in the previous 24 months
6.3.3. Occurred during the night, during early morning, or upon exercising in the intervals between exacerbations at any time in the previous 12 months
6.3.4. Where allergic exacerbations can be clinically related to an allergen exposure WITH a corresponding positive SPT or SpIgE to allergen
7. Written informed consent to participate.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 62; UK Sample Size: 62

Total final enrolment
62

Key exclusion criteria
1. Children and/or families who are unable to comply with the regime of 24 weekly injections and clinic visits
2. Evidence of underlying immune compromise, autioimmune disease, immune complex mediated conditions
3. Malignancy or a history of malignancy
4. Preexisting hepatic or renal impairment

5. Known cardiovascular or ischaemic cerebrovascular abnormality
6. Other serious or uncontrolled systemic disease
7. Pregnancy or lactation
8. Known history of hypersensitivity or anaphylaxis to anti-IgE injections or its constituents
9. Insufficient understanding of the trial assessments
10. Participation in a CTIMP in the previous 60 days or (if known) 4 half-lives of the relevant medication, whichever is the greater. In this case, entry may be delayed until the appropriate time
11. Investigator feels that there is a good clinical reason why the child would be unsuitable to participate in the study

Date of first enrolment
20/11/2014

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St. Thomas' NHS Foundation Trust
St Thomas's Hospital
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's & St Thomas' NHS Foundation Trust & King's College London (Comprehensive)

Sponsor details
Imaging Sciences
The Rayne Institute
Lambeth Wing - 4th floor
St Thomas' Hospital
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

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

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/03/2017		Yes	No

Statistical Analysis Plan	statistical analysis plan	23/05/2017		No	No
Results article	results	25/11/2019	07/08/2020	Yes	No
HRA research summary			28/06/2023	No	No