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Trial of eczema allergy screening tests

Submission date
23/07/2018

Recruitment status
No longer recruiting

Registration date
30/07/2018

Overall study status
Completed

Last Edited
23/08/2023

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Many parents worry that food allergies cause eczema. If a food causes sudden, severe reactions then that food should be avoided. However, for children who “just” have eczema, it is not known whether avoiding certain foods makes any difference to eczema symptoms. Allergy tests are imperfect and experts disagree whether they should be offered. Patients and doctors agree that this problem is a research priority. This study will help decide whether routine allergy tests for children with eczema are helpful or not. The best way to do this is in a clinical trial. Because of the lack of research in this area, the researchers want to first run a smaller version of what the main study might look like.

Who can participate?
Children aged between 3 months and 5 years with eczema

What does the study involve?
Participants are randomly allocated to receive either usual care from their GP or to be asked extra questions and offered skin prick allergy tests. This involves “pricking” small drops of six common allergy-causing foods (cow's milk, peanut, hen's egg, codfish, wheat and cashew) into the skin and noting any local reaction (swelling). If the results are unclear, some children need to be observed eating some of the food(s) at their local hospital or a trial of exclusion/introduction at home. Depending on what the tests show, parents are told what foods are "safe" or should be avoided. Children are followed up for 6 months and some parents and GPs are interviewed to find out what they think about the tests and the study itself.

What are the possible benefits and risks of participating?
The results of this study will be used to design a bigger study. The researchers will also have a better understanding of what parents and GPs think about food allergies and tests in children with eczema. It may be that food allergy testing is not helpful. In addition, the child may experience side effects or have a reaction to either the skin prick tests or the oral food challenges. Parents/carers can decide to stop taking part in the study at any time. By taking part in the study, parents/carers are asked to give up time to meet with a researcher twice over a period of 6 months for the assessments. At the first visit, they are asked to meet the researcher at the child’s GP Practice. At the second and final visit the researcher will try to meet them at a

time and place which is convenient (at home, for example). Parents/carers will also be asked to complete monthly surveys regarding their child's eczema symptoms and use of other eczema treatments.

Where is the study run from?
United Hospitals Bristol NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2018 to November 2019

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

Who is the main contact?
1. Dr Kirsty Roberts
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2. Dr Matthew Ridd
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
37831

Study information

Scientific Title
The TEST (Trial of Eczema Allergy Screening Tests) study: feasibility randomised controlled trial with economic scoping and nested qualitative study

Acronym
TEST

Study objectives
What is the clinical (disease severity) and cost-effectiveness of routine food allergy testing plus advice compared to current standard practice for the management of eczema in children?

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - South Birmingham Research Ethics Committee, 05/06/2018, ref: 18/WM/0124

Study design
Randomised; Interventional; Design type: Diagnosis, Process of Care, Dietary, Other

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Dermatology; UKCRC code/ Disease: Skin/ Dermatitis and eczema

Interventions
TEST is a single centre, two-group, individually randomised (1:1) feasibility RCT with economic scoping and nested qualitative study set in primary care in the West of England.

The study will recruit children with eczema aged 3 months to 5 years by postal invitation from their GP and opportunistically during appointments at the surgery.

INTERVENTION GROUP 'ALLERGY GROUP':

The CSO will first take a structured allergy history. Next, the CSO will carry out the SPTs from a standard panel of cow's milk, peanut, hen's egg, codfish, wheat & cashew (allergens commonly associated allergies in young children with eczema with eczema), along with positive (histamine) and negative (saline) controls. Sharp lancets will be used to prick drops of allergen (and one positive and one negative control) into the skin (forearm, outer upper arm or back). The diameter of any wheal reaction will be measured in millimetres after 15 minutes. Depending on the participant's allergy history and the results of their skin prick test, the parent participant will be either reassured and advised to follow a normal diet; or told to exclude any food(s) to which they have had a "positive" result.

Of those children with a "positive" result, some will be invited to repeat their SPT, referred for an OFC and/or to undergo a home dietary trial of exclusion or inclusion. If required, OFCs will usually be undertaken within 1-2 weeks of the baseline appointment as part research study, at a local Clinical Investigation Unit in UHBristol NHS Foundation Trust, by trained and qualified nurses. OFCs will be undertaken as per standard practice at UHBristol, there will be no modification to the procedure for the purposes of the research.

Advice will be tailored accordingly for mothers who are breast-feeding and/or babies who have not yet been weaned. Any participants with indeterminate results will be reviewed by an expert allergy panel and advice on food ingestion/avoidance relayed to their family accordingly.

CONTROL GROUP 'USUAL CARE':

Participants in the control group will not receive any additional assessments or tests. Care after allocation will be as usual, described in the NICE eczema and allergy in children guidelines. Any allergy tests and subsequent advice will be monitored as part of this feasibility study.

Regardless of allocation, all management after randomisation, including investigations and/or referrals for possible new, incident food allergies, will remain under the care of the participant's GP.

Intervention and control groups will complete and monthly parent reported diary every 4 weeks for 24 weeks of the state and bother of their eczema, quality of life, food ingestion and allergy symptoms and adverse events. Parents will be given the option of completing follow-up questionnaires either online or on paper (freepost). Those who choose to provide data online will receive email prompts, while those who opt to complete on paper will be offered SMS reminders when their questionnaire is due. All parents will receive SMS and/or telephone reminders when questionnaires are overdue. For those parents who struggle to complete the questionnaires or for those returned with missing data, an option to complete these over the telephone will be offered.

Both groups will have a final face-to-face follow-up assessment at 24 weeks with participant and their carer at a venue of their choosing, usually their home.

QUALITATIVE INTERVIEWS (participants and GPs):

In-depth, cross-sectional qualitative interviews will be conducted either by telephone or face-to-face, depending on the preference of the interviewee. All parents and GPs at participating surgeries will be asked whether they are willing to be contacted to take part in an interview. Purposive sampling will be used to help ensure maximum variation of the parent and GP samples.

Parents will be sampled from both intervention and control groups, with the former over-sampled to explore the acceptability of the intervention across parent groups. Further purposive criteria for parent interviews are mild/moderate (<17) vs severe (≥17) POEM symptom score (using most recent data available), socio-economic status (assessed via postcode, using the Index of Multiple Deprivation Database (categories: high (8-10)/medium (5-7)/low (1-4)), and length of time in the trial (shortly after baseline visit or OFC, or later in the trial). For participants in the intervention group, we will seek to speak to parents of children with negative, positive and (in the case of SPTs) ambiguous test results. Sampling of GPs will capture diverse populations served by practices and length of time in the trial (baseline, during, after).

The number of interviews will be guided by the research questions, and sampling will stop when we have sufficient "information power" relevant to the study aims. We anticipate a total of 20 parent and 10 GP interviews.

In addition, we will conduct brief telephone interviews with ~5-8 parents who have decided to decline to take part in response to the initial invitation letter or later withdrawal from the trial, but indicate that they are willing to discuss reasons why.

Parents will be informed about the qualitative component of the study in the trial information sheet provided with the invitation to participate. Parents declining to take part in the trial will have the option to agree to be contacted for possible interview as part of the invitation and response letter. At the baseline assessment and consent visit, parents will be asked to indicate whether they are happy to be approached regarding participating in an interview, and if so the best way to contact them and to send them further information. This will generate a pool of potential interviewees for sampling for the qualitative interviews. Once parents have been selected for invitation for an interview, the qualitative researcher will send the parent an invitation to participate, information sheet and consent form via email or post. The researcher will then contact the parent by email or phone to determine consent and arrange the interview.

GPs will be invited to participate in an interview by an initial email from the research team with an information sheet and consent form. GPs willing to be approached will be contacted by the research team by email or phone to determine consent and arrange the interview.

All interviewees will have received an information sheet and consent form to read in advance of the interview. Written informed consent will be taken in face-to-face interviews, and verbal consent will be taken for telephone interviews. The researcher will verbally explain consent to the participant before the interview starts and, if the participant confirms their agreement to the interview, the verbal consent agreement will be repeated, and audio recorded. Verbal consent is considered standard practice in studies where telephone interviews are conducted and has been used previously in several HRA-approved BRTC-portfolio trials across a range of clinical populations, e.g. UPSTREAM, CEDAR, HepCATT and RADAR. Verbal consent reduces burden and is resource-efficient, as it removes the need to send and return paperwork.

Topic guides have been developed, based on the focus of the trial and existing research literature, and refined with input from the study's Public and Patient Involvement (PPI) group.

However, flexibility will be maintained, and topic guides modified over the course of different interviews (where appropriate) to enable exploration of new issues that arise throughout this process.

Intervention Type
Other

Primary outcome(s)
The feasibility of conducting the trial (recruitment, retention, contamination) and collecting the required data:
1. Recruitment and retention rates compared by method of recruitment and participant characteristics
2. Acceptability of recruitment, intervention and follow-up procedures to parents/carers
3. Acceptability of trial processes and procedures to GPs
4. Development and refining of a manual on the interpretation and dietary advice to be given according to allergy history/skin prick test +/- oral food challenge +/- home dietary trial findings, with accompanying patient information leaflets
5. Number of participants In the intervention group with positive/negative structured allergy histories, skin prick tests and oral food challenges/home dietary trial (where done), to inform estimates for the main trial
6. Adherence to dietary advice
7. Contamination of the control group
8. Acceptability and feasibility of collecting clinical outcomes to determine the primary outcome of the definitive trial
9. Feasibility and optimise collection of patient-level data on NHS and personal resource use
10. Feasibility of using the CHU-9D in children under 5 years of age
11. Inform eligibility criteria for the future definitive trial
12. Detection bias in the collection of patient-reported outcomes
13. Test trial processes and logistics

Key secondary outcome(s))
1. Eczema symptoms, measured using POEM at baseline and weeks 4, 8, 12, 16, 20 & 24
2. Eczema signs, measured using EASI at baseline and week 24
3. Eczema 'bother' score, measured using single item categorical score 0-10 at baseline and weeks 4, 8, 12, 16, 20 & 24
4. Itch intensity score, measured using single item categorical score 0-10 at baseline and weeks 4, 8, 12, 16, 20 & 24
5. Parent global assessment of eczema, measured using single item categorical score 0-4 at weeks 4, 8, 12, 16, 20 & 24
6. Other possible symptoms of food allergy, measured using unvalidated questionnaire at baseline and weeks 8 and 24
7. UK diagnostic criteria for atopic dermatitis, measured at baseline
8. Main carer anxiety, measured using GAD-7 at baseline & 24 weeks
9. Diet of child and/or mother if child being breastfed by her, measured using unvalidated questionnaire at baseline and weeks 4, 8, 12, 16, 20 & 24
10. Adverse events, measured using unvalidated questions at baseline through to week 24
11. Child and family quality of life, measured using ADQoL, CHU-9D and IDQoL at baseline and weeks 8 and 24
12. Satisfaction with trial processes, procedures and paperwork, measured using unvalidated exit questionnaire at 24 weeks
13. Health services utilisation, measured using unvalidated questionnaire at weeks 4, 8, 12, 16,

20 & 24, and electronic medical record review at week 24
14. Out-of-pocket expenses/time off work, measured using unvalidated questionnaire at weeks 4, 8, 12, 16, 20 & 24

Completion date
31/01/2020

Eligibility

Key inclusion criteria
Children must:
1. Be aged between 3 months and less than 5 years
2. Have eczema diagnosed by an appropriately qualified healthcare professional (registered doctor, nurse or health visitor)
3. Mild, moderate or severe eczema (Patient Orientated Eczema Measure (POEM) score>2)

The person giving consent must:
1. Have parental responsibility for the participant
2. Be willing for their child to have allergy skin prick tests (SPTs) and oral food challenges

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 months

Upper age limit
5 years

Sex
All

Total final enrolment
84

Key exclusion criteria
Child:
1. Medically-diagnosed food allergy or awaiting referral/investigations for possible food allergy
2. Previous investigations for food allergy (does not include home testing)

The person responsible for consent:
1. Is unable to give informed consent
2. Has insufficient written English to complete outcome measures
3. Has another child in the family already taking part in the trial

Date of first enrolment
01/09/2018

Date of final enrolment
28/02/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
United Hospitals Bristol NHS Foundation Trust - Children's Hospital
Bristol
United Kingdom
BS1 3NU

Study participating centre
12 GP practices, yet to be determined
Bristol, North Somerset and South Gloucestershire
United Kingdom
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR School for Primary Care Research; Grant Codes: 383

Results and Publications

Individual participant data (IPD) sharing plan

Requests for anonymised, individual participant level data should be made to Dr Matthew Ridd (m.ridd@bristol.ac.uk) (Chief Investigator) after November 2020. Access for secondary analyses (e.g. individual patient data meta-analyses) must be within the remit of parent/carer consent for data re-use.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2021	04/01/2021	Yes	No
Protocol article	protocol	09/05/2019	13/05/2019	Yes	No
HRA research summary			26/07/2023	No	No
Other publications	qualitative interview study within the Trial of Eczema allergy Screening Tests (TEST) feasibility trial	18/11/2020	23/08/2023	Yes	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