The Trial of Eczema allergy Screening Tests (TEST) Study

TEST
Trial of Eczema allergy Screening Tests

Participant Information Sheet

We would like to invite you and your child to take part in a research study

- Before you decide whether to take part, it is important to understand why the research is being done and what taking part will involve for you and your child.
- Please read the following information carefully and take time to decide whether you wish to participate.
- You are free to decide whether to join the study. If you choose not to take part, this will not affect the care you get from your GP (general practitioner).
- Please ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information sheet.

Important things you need to know

- Your child has been asked to take part because they have eczema and they are between three months and five years old.
- While food allergy is more common in people with eczema, for most children it is not thought to make their eczema worse. Parents often ask about tests for food allergy and it is not clear when food allergy testing might be helpful.
- To test if food allergy testing can help children with eczema, we need to compare two groups in a large study: one group who gets allergy testing and advice; and another group that doesn't.
- In TEST, we want to find out if such a study (clinical trial) is possible.
- If your child is put into the allergy test group, they will have a skin prick test. This is when a solution containing the relevant foods to test are 'pricked' into the skin. Your child may also be asked to eat one or more foods that commonly cause allergy. This will be done under controlled conditions (in hospital).
- Regardless of which group your child is put in, we will follow your child up for 6 months.
- We may ask to talk to you in more detail about your experiences and opinions, but this is optional.

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How to contact us

If you have any questions about this study, please email, ring or write to:

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1 Why we are doing this study

What are we studying?

Eczema is a common childhood condition where the skin is dry and itchy. It is usually diagnosed in the first two years of life. In the UK, most children are treated by their GP.

Eczema tends to flare up/get worse and there are many reasons why a worsening or "flare" of eczema can happen. Many parents worry about food allergies. Research is limited but suggests that food allergies are not the cause of eczema flares in most children. In the NHS, when your doctor thinks it may be helpful to do allergy tests, it usually involves referral to a specialist at the hospital and often a long wait to see the specialist.

One form of allergy test, called the skin prick test, could be carried out by a trained nurse at your child's general practice. Together with specific questions about allergy symptoms and, for some children, follow-on tests at the hospital, your doctor might be better able to advise you on whether allergy may play a part in your child's eczema.

In the TEST study, we want to find out if doctors and families of children with eczema would be willing to take part in a study to find out whether this type of allergy testing is a helpful thing to do or not.

2 How the study works

How do we find out whether food allergy testing can help?

To compare how effective allergy testing is, we are carrying out a study to test the feasibility of a large clinical trial. We plan to include 80 children with eczema, aged between 3 months and 5 years. They will be divided into two groups: 'usual care' and 'allergy testing'.

If your child is put into the 'usual care' group, they will have the care for their eczema that they would normally receive from their GP.

If your child is put into the 'food allergy testing' group, a research nurse will ask some more questions about your child's symptoms and then carry out skin prick tests. Depending on the results of these tests your child may then be asked to eat one or more foods that commonly cause allergy under controlled conditions (in hospital) or exclude the foods for in a home trial 2-4 week period and then re-introduce them.

Regardless of which group your child is put in, we will follow your child up for 6 months. We will ask monthly about your child's eczema, diet and any symptoms of allergy. This will help us to know if the eczema gets better or worse and if this may be related to any food allergies. It is important to collect this information regularly because eczema can change quite a lot over time.

At the first visit and 6 months later, a research nurse will also assess the appearance of the eczema mainly by looking at the redness and how much of your child's body is affected.

After all participants' data has been collected, we will analyse this information to see whether it is feasible to do a large study to determine whether food allergy testing can improve eczema. This kind of comparison looks at everyone in the study at the same time, rather than looking at individual children. It is not possible to identify anyone from these results and the information is kept confidential.

How is it decided who gets an allergy test and who doesn't?

In this kind of study, neither the researchers, nor your GP, nor you get to choose which group your child gets put in. It is done using a computer, by a process called 'randomisation'. It's a bit like rolling a dice and it means that there is an equal chance of being allocated to 'usual care' or 'food allergy testing'.

The rest of this leaflet explains how you might be involved in our research study.

3 Why is your child being asked to take part?

Your GP practice is supporting this study and your GP thinks your child may be suitable for the study. We have asked you and your child to take part because your child has a history of eczema and is aged between 3 months and 5 years.

4 What will happen if we choose to take part?

Enrolling you in the study

We have sent you this additional information because you have told us that you are interested in learning more about this study. If you would like to take part, the next step is to meet with one of the researchers at your GP Practice. You can then decide if you and your child would like to join the study.

First research visit

The research nurse will contact you and after confirming your child's eligibility, will arrange an initial assessment visit. If your child is taking antihistamine medicine, they will need to stop taking it at least three days before your first research visit.

The visit will take up to 60 minutes. At this appointment, the researcher will explain the study and complete some study paperwork with you, including a consent form.

We will ask questions about your background, your child's eczema symptoms, how eczema affects you and your family, and how well you and your child have been feeling. The research nurse will also examine your child's skin.

Your child will then be allocated by chance to either receive 'usual care' from your GP or proceed with the food allergy tests.

You do not have to enter the study unless you feel completely happy with what you are being asked to do. If you are not eligible or do not want to take part, you will continue to receive the same care from your GP.

‘Usual Care’ Group

If your child is allocated to the ‘usual care’ group they will remain under the care of their GP as they would normally for their eczema.

Follow-up diary

We will ask you to record your child’s symptoms, diet, any contacts with healthcare professionals and time off work because of your child’s health every month for up to 6 months. Some months we will also ask you about you and your child’s quality of life. This may take up to 10 minutes each month. You can choose whether to complete these using a secure online diary or a paper questionnaire. Whatever method you choose, the research team will send you a reminder when the next survey is due.

The questionnaire at the end of the study, at 6 months, will be a bit longer than others in the study. It might take up to 15 minutes to complete. It will include the same questions as the monthly surveys, plus some extra questions about how well you and your child have been feeling, and your experiences in the study.

Follow-up by research team

We also ask that you and your child meet the researcher at the end of the study, 6 months after the initial visit to re-assess their skin. This appointment will be at a time and place convenient for you and will normally take 15-20 minutes to complete.

Taking part in the study will not stop you or your GP changing your child’s medication or any other therapy, if this is what you want or decide is the best thing to do.

Electronic medical record review

On the consent form, we will ask for your permission for us to review your child’s medical records at the end of the study (for healthcare appointments and medications prescribed). This is important for helping us understand the full impact of allergy testing. If you agree, any information we record will have your child’s name and address removed so that they cannot be recognised from it.

Interviews about your experiences

We are also interested in finding out your views on taking part in this study. We would like to interview around 20 people. Interviews will be face-to-face or by telephone and will include people who are taking part in the study (as well as some people who decide not to continue with the study). If you are invited and want to do this part of the study, we will go through what this would involve and ask for your additional consent first.

Food 'Allergy Testing' Group

If your child is allocated to the Food 'Allergy Testing' group you will be asked additional questions about your child's symptoms and you will be offered a skin prick test for your child.

Skin Prick Test

Skin prick tests will be offered for a range of foods: cow's milk, hen's egg, wheat, peanut, codfish, and cashew nut. During the test, a nurse will place a drop of the relevant food on your child's skin, usually their forearm, outer upper arm or back. The skin under the drop is then 'pricked' with a lancet, which is a sterile metal stick with a small point on the end that scratches the top layer of the skin. This helps the allergen to get under the skin surface. The skin prick test may be slightly uncomfortable when the skin is pricked, but it should not hurt. The nurse will then wipe away the drop and repeat the same process for each allergen. With a washable pen, the nurse will make a mark on your child's skin to identify each test. After 15 minutes, the nurse will check your child's skin for a reaction.

If your child has no reaction, the skin under the drop will remain normal. If your child has a positive reaction, the skin under the drop will become red and itchy – usually a white, raised swelling surrounded by a red area ('wheal'). This will fade after a few hours.

If the test is positive, the wheal may feel itchy but will usually start to settle after 20 minutes. A cold compress/ice pack can be used on the area to help relieve the itching if your child is upset. You can also give your child some antihistamine medicine after the test is finished.

Depending on the combined results of the skin prick test and the questions about your child's symptoms, you will be offered onward treatment:

- If your child has a negative skin prick test and no relevant symptoms, you will be advised to follow an unrestricted diet.
- If your child has positive skin prick test and/or symptoms to one or more foods, you will be advised to avoid that food in your child's diet.

If the findings of your child's symptoms or one or more of your skin prick tests are ambiguous, you will be offered:

- repeat skin prick test(s) and/or
- appointment(s) for an Oral Food Challenge (see next page) and/or
- home dietary trial

After the results of these additional tests, you will be advised whether to include or exclude the food from your child's diet.

Follow-up by research team

Whatever the results of your tests, just like children in the "usual care" group, we meet with you for a second visit at 6 months and will ask you:

- to complete a diary every 4 weeks
- to meet with the research nurse at 6 months
- for permission to review your child's electronic medical record
- we may ask if we can interview you about your experience.

All the above will be the same as for children in the 'usual care' group (see page 4).

Follow-up after the study

If a food allergy is diagnosed some children may require follow-up after the study has finished. This may be either from a dietitian or the local allergy team. We will let you know if we think this is necessary and ask your GP to arrange it for you.

Oral Food Challenge

An Oral Food Challenge is done in hospital to find out if your child is allergic to or able to eat a particular food.

In the TEST study, you will be offered an appointment for an Oral Food Challenge if your child's symptoms or skin prick tests are ambiguous. The Oral Food Challenge will take place on the Puzzle Wood ward at Bristol Royal Children's Hospital. Puzzle Wood is a small ward area with only 4 beds, a waiting area and a play area.

We aim to offer an appointment within two weeks of your first research visit. However, only one food can be assessed at each appointment, so it is possible you may need more than one appointment if your child's results were ambiguous for more than one food.

What is a Food Challenge?

An Oral food challenge is when a certain food is fed to your child under close medical supervision. Over the course of a morning your child will be gradually given bigger doses of the food, until a reaction occurs or the 'top dose' is eaten without any symptoms. The 'top dose' is what a child would be expected to eat as a normal portion. You should be aware that an Oral Food Challenge can take up to 6 hours.

What happens during the food challenge or supervised feed?

First, an allergy nurse will check that you understand the test, including the risks and benefits, and answer any questions that you have. They will then ask you to sign a consent form.

Next, a nurse will take your child's temperature, pulse and blood pressure. We will continue to monitor these throughout the test. Then, over the course of the morning your child will be given increasing amounts of the challenge food every 20 minutes.

The amount of food given varies according to the food being tested. We often hide the challenge food in a familiar food to make sure they eat the required amount.

Your child will be checked for signs of an allergic reaction before each dose of food is given. If your child has a definite allergic reaction at any point, the test will be stopped. We will treat your child with the necessary medication and observe them until they are better and able to go home. This will be for at least 2 hours.

What are the benefits of having an oral food challenge?

An Oral Food Challenge will confirm whether your child has an immediate-type allergy to a particular food. If your child completes the food challenge without a reaction, they should be able to reintroduce that food into their normal diet. If they are found to be allergic, then the hospital will ensure that they are given a management plan and appropriate medications. You can then pass this information on to your child's nursery or school.

Are there any risks associated with having a food challenge?

There is a potential risk that your child will have a reaction to the food they are being challenged to. This is why the test will be done in hospital where all emergency medications for an allergic reaction will be prescribed and prepared for your child in advance. Your child will be closely observed by a nurse who will monitor them for any signs of an allergic reaction, such as an itchy rash or breathing difficulties. If your child does have an allergic reaction the test will be stopped and appropriate medication will be given to relieve the symptoms and to stop the reaction getting any worse. This is most likely to be an antihistamine but or in the case of a more severe reaction, may include a Salbutamol nebuliser or adrenaline (e.g. EpiPen).

What are the alternatives to my child having a food challenge or supervised feed?

You may choose for your child not to have an oral food challenge and just avoid the food they may be allergic to. However, a food challenge is the only safe and definitive way to find out whether your child has a specific food allergy or not.

What should I do to prepare my child for the food challenge?

Appropriate to the age of your child, it is important to prepare your child for their challenge, so that they understand what is happening to them. This can help with their willingness to cooperate. You should give your child truthful information. Explain that your child will meet nurses and doctors and that they will be there for about half a day.

Please feel free to bring familiar toys with you to help your child feel at ease. They can eat normally when the test is completed so please bring a packed lunch for your child to eat.

In some cases, you will be asked to bring the test food with you. This will be clearly explained in your appointment letter. We will offer reimbursement of travel expenses and any associated childcare costs, for example for other children on the day of the appointment.

It is essential that your child is well at the time of their challenge and that they have not taken any medicines containing antihistamines for one week before the challenge or supervised feed.

5 How is taking part in the study different from usual care?

The main difference will be that your child may be offered food allergy testing depending on which group they are allocated to. Such allergy tests are not routinely offered, and when they are offered, they are usually done in specialist allergy clinics at hospital. If you decide to take part in this study and your child is put in the food allergy testing group, your child will have the skin prick test at your GP practice by a qualified and trained research nurse.

You will also be asked to complete monthly diaries and to meet with the research nurse at 6 months. This is described in Section 4, "What will happen if we take part?"

While taking part in the study, your child will continue to be looked after by their GP as normal. You can take your child to see their GP as often as you think necessary. No treatment will be withheld from your child during the course of this study.

6 Possible benefits and disadvantages of taking part

What are the possible benefits of taking part in the TEST study?

Most people find it rewarding to take part in medical research and appreciate the additional monitoring and contact with the researchers.

This research will help doctors in the future to decide if food allergy testing should be recommended for children with eczema.

What are the possible disadvantages and risks of taking part in the trial?

This study is a randomised clinical trial and, therefore, you cannot choose if your child receives food allergy testing or not. This will be determined by chance using a computer.

It may be that you do not find food allergy testing helpful for your child. In addition, your child may experience side effects or have a reaction to either the skin prick tests or the Oral Food Challenges. You can decide to stop taking part in the study at any time, even if you have been allocated to the 'food allergy testing' group and you are in the middle of the tests.

If you think your child develops any problems because of the study, you should record this in your diary and discuss it with your GP.

If you decide to take part in the study, you will be asked to give up some time to meet with a researcher 2 times over a period of 6 months for the assessments. At the first visit, you will be asked to meet the researcher at your child's GP Practice. At the second and final visit the researcher will try to meet you at a time and place which is convenient for you and your child (your home, for example). You will also be asked to complete monthly surveys regarding your child's eczema symptoms and use of other eczema treatments.

7 More information about taking part

Do we have to take part?

No, it is up to you to decide whether to take part. Invitation letters have been sent to all children who might be able to take part from your GP practice. If you choose to the join the study, you are free to withdraw from it at any time, without giving a reason. This would not affect the standard or type of care your child will receive.

Will I receive any payment for taking part?

No, we are not able to offer any expenses or payments to patients who participate in the study. We will, however, offer a £10 voucher at the beginning and another £10 voucher part-way through the study to thank you for your time. We will also offer your child a small gift.

What happens if new information becomes available during the study?

During a study, sometimes new information becomes available about the treatment being studied. If this happens, the research team will tell you and discuss whether you want to continue in the study.

If you decide to stop taking part in the study, your usual care with your GP will continue. If we think your child should withdraw from the study, we will explain the reasons and arrange for their normal care to continue.

What happens when the study stops?

Very occasionally, a study is stopped early. If this happens, the reasons will be explained to you and arrangements made for your GP care to continue as usual.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researcher or trial manager who will do their best to answer your questions. Alternatively, you could speak to the Chief Investigator, Dr Matthew Ridd (email: m.ridd@bristol.ac.uk, telephone: 0117 331 4557).

If you remain unhappy and wish to complain formally, the normal NHS complaints process is available to you.

What insurance is in place for the study?

The University of Bristol has arranged insurance to cover the legal liability of the University as Research Sponsor in the event of harm to a research participant as a result of the management of the research by the University.

The University of Bristol holds Professional Negligence insurance to cover the legal liability of the University, for harm to participants arising from the design of the research.

This does not affect the responsibility of the NHS or the participant's GP practice for clinical patient care.

What will happen to information about me/my child collected during the study?

All information will be held securely and in strict confidence. We keep the information we collect about your child separate from their personal details and we can only link this information together with a secure code. Only authorised members of the research team will have access to the information.

We will keep personal data about you and your child for up to 12 months after the study has ended. We will keep anonymised research data collected throughout the study for 5 years. After the study has finished, the study database will be 'locked' (data can no longer be added or changed). Study data will be kept in a secure location and available on request for audit and inspection by regulatory bodies. The Chief Investigator is responsible for authorising retrieval and disposal of archived material.

The personal details we will need to collect from you if you decide to take part are yours and your child's name, your contact details (address, telephone number and e-mail address), and your child's date of birth, gender, NHS Number and the name of their GP. The purpose of collecting this data is so we can keep in touch with you during the study and to inform your GP that your child is taking part in the study and update them with any test results if your child is randomised to the 'food allergy testing' group. The personal details which we would collect from you is not part of a legal requirement and there will be no consequences should you decide to not take part and not provide this data.

The name of the person who is in charge of collecting the information is called the Data Controller who is Dr Matthew Ridd (email: m.ridd@bristol.ac.uk, telephone: 0117 331 4557) should you wish to contact them about the information that is collected during this study. If you have a concern of how yours and your child's information is used during this study you can also contact the ICO (https://ico.org.uk or telephone: 0303 123 1113).

The research team will occasionally need to allow monitors from Regulatory Authorities to inspect the study paperwork, in order to meet legal, ethical and safety requirements. All individuals who have access to data will be bound by strict data protection and confidentiality rules. Only if the researcher had concerns about the well-being of you or your child would they be obliged to report this to the relevant authorities.
We will use the information we collect to look at how best to help children with eczema. We will keep it for up to 5 years after the end of the study and then destroy it securely.

What is open access?

At the end of the study, your data may be made "open access". This means that it will be stored in an online database so that it is publicly available. However, all data is anonymised. This means that an identification number is used for you and your child. It will not be possible to identify you or your child by name from any aspect of documentation or reporting for this research study.

Open access of research data and findings is considered best scientific practice. It is a requirement of many funding bodies and scientific journals. As a large proportion of research is publicly funded, the outcomes of the research should be made publicly available. Sharing data helps to maximise the impact of studies through wider use, and encourages new avenues of research.

What will happen if my child or I don't want to carry on with the study?

You can stop taking part in the study at any stage, but we would still like you to complete the follow-up surveys so that we can monitor your progress. If you don't want to carry on with the study assessments, however, you can completely withdraw from the study. The clinical information already collected will still be used but it will be anonymised if you decide to completely withdraw and all personal data will be destroyed.

Involvement of your GP

Your GP is supporting this research. If you join the study, we will tell your child's GP that he/she is taking part. Your child may be offered food allergy test(s) depending on their allocation. Otherwise, your child will receive the same care as they are currently getting from your GP practice.

What will happen to the results of the study?

When the study is completed, the results will be published in a journal, so healthcare professionals can learn about the main findings. If published, the identity of you and your child and all personal details will be kept confidential. No named information about you or your child will be published in any report about this study. We will also provide you with a summary of our findings from the study, if you wish.

Who is organising and funding the study?

This trial is organised by the University of Bristol. The funder is the School for Primary Care Research, which is part of the National Institute for Health Research. The trial has not received any funding, samples or promotional materials from the pharmaceutical industry.

Who has reviewed the study?

This trial has been reviewed by an independent group of people, called the Research Ethics Committee, to protect your safety, rights, well-being and dignity. The study has been reviewed by the Health Research Authority and given a favourable opinion by the NHS REC (West Midlands – South Birmingham Research Ethics Committee, Reference Number 18/WM/0124).

8 Contact for further information

If you have any questions regarding the study or how you might be involved further, please contact one of the research team below:

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Thank you for taking the time to read this leaflet and for considering whether to take part in this study