

INFORMATION SHEET

Beating Egg Allergy Trial (BEAT).

The effect of early introduction of egg into the diet of infants at high risk for atopy and subsequent egg allergy: A double blind randomised control study.

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We would like you to consider participating in a research study that will be conducted in the Department of Allergy and Immunology at The Children's Hospital at Westmead.

What is the study about?

An allergy is when the body has a reaction to a protein (e.g. foods, insect stings, pollens) or another substance (e.g. antibiotic). These substances are called allergens. Common things that people are allergic to include food (e.g. peanuts, nuts, shellfish, milk, eggs, wheat and fish), pollens, grasses, house dust mite and animals or insect stings. Most immediate type allergic reactions are caused by a reaction between a protein in the blood called Immunoglobulin E (IgE) and the allergen.

Allergy to foods may cause skin problems such as hives and itch or bowel problems such as tummy pain, vomiting or diarrhoea. Occasionally, people may develop problems with their breathing passages or lungs e.g. swelling of the tongue, cough, hoarse voice or wheeze. This severe allergic reaction is known as anaphylaxis. In some people with eczema, their eczema may get worse if they eat a food they are allergic to.

Previously, many doctors thought that introducing certain foods early into a baby's diet may cause food allergies, especially in babies who have a parent or sibling with an allergy. We therefore recommended avoiding giving these foods to babies. Despite this, the number of children with food allergies has significantly increased. The Australian Society for Allergy and Clinical Immunology (ASCA) and other allergy organisations around the world now recommend introducing solids from 4-6 months of age, but there is no evidence to recommend either early introduction or avoidance of foods such as egg and peanut butter.

Results from research suggest that for some foods, early introduction may protect a child against developing food allergy. For example, researchers in the UK are investigating whether early introduction of snacks containing peanut reduces the risk of peanut allergy in childhood. Some studies have suggested that early introduction of egg may be beneficial in reducing the development of food allergy to egg, but they are not conclusive.

We would like to find out if introducing egg protein into the diet of children from 4 months of age reduces the risk of them developing food allergy and other associated conditions, such as eczema.

Who can participate in the study?

Any child under 4 months of age, who has at least one parent or sibling with an allergy (food allergy / asthma / eczema / hayfever / allergic rhinitis, can participate in the study.

What will the study involve?

If you agree for your child to take part in the study, you will need to attend a clinic with your child when they are 4, 8 and 12 months old, in order to see a Paediatric doctor specialising in the management of Allergy.

These appointments will involve some **allergy tests**, called a skin prick test. In a skin prick test, a small drop of a protein extract is placed on the skin (usually the forearm) and a small prick is made in the skin through the drop. Most children do not find skin prick tests to be painful. The size of the swelling (wheal) is measured after 10-15 minutes. A skin prick test which results in a wheal (hive) bigger than 2mm is positive. If the skin test is positive, this means they are sensitised to that food i.e. their body has produced IgE allergy antibody against that food protein. It means they could have an allergic reaction if they eat the food, but it does not always mean they will have an allergic reaction if they eat that particular food.

At 4 months of age:

You will be asked to attend the Allergy clinic, where your child will have a full allergy assessment, which involves skin prick tests, performed by an Allergy doctor. If the test is positive, indicating your child is sensitised to egg, then your child will not be able to take part in the study. Instead, you will be given the option of receiving ongoing advice and management through the Allergy Service at The Children's Hospital at Westmead.

If the skin test is negative and the doctor decides that it is appropriate for your child to take part, you will be given a powder to take home. After introduction of the first weaning food for your child (between 4 and 6 months) you then start feeding this powder to your child mixed with either with some water or expressed breast milk or the weaning food and feed this to your child every day until they are 12 months old. This powder will either be freeze-dried pasteurised egg protein or rice powder. A computer will decide which powder you receive. Neither you nor the doctor will be told which powder is to be used. The reason for this is to avoid any unfairness in the study. The first dose of this powder will be given to your child at the clinic visit, in order to make sure your child is able to tolerate it.

You will also need to avoid all egg in your child's diet until they are 8 months old (except for the powder). The doctor will give you information on how to do this.

At 8 months of age:

You will be asked to attend the Allergy clinic, where your child will have a full allergy assessment performed by an Allergy doctor and some allergy skin prick tests performed. If any of these tests are positive, then the doctor will give you appropriate advice and you will be offered the option of being managed by the routine Allergy Service at The Children's Hospital at Westmead.

From then onwards, you will be free to give your child any food of your choosing, though you will need to continue to give him/her the powder with some water or expressed breast milk on a daily basis.

At 12 months of age:

You will be asked to attend the Allergy clinic, where your child will have a full allergy assessment performed by an Allergy doctor and some allergy skin prick tests performed. If any of these tests are positive, then the doctor will give you appropriate advice and you will be offered the option of being managed by the routine Allergy Service at The Children's Hospital at Westmead. This may include being offered an in hospital observed egg challenge, if it is not clear whether your child has egg allergy.

On this final occasion, we will also perform another type of allergy test which involves a blood sample. We will need to collect 2mls of blood (under half a teaspoon) from a vein in your child's arm. This statement is made in a subsequent paragraph so can be removed from this one

Are there any benefits for my child participating in the study?

By taking part in this study, your child will receive an allergy assessment and if there are any concerns, you will be given appropriate advice and the option of returning to the Allergy Clinic for ongoing management.

Otherwise, there are no known benefits for your child in participating in this study. We hope that the results from this study will allow us to give advice to other parents based on evidence as to whether to introduce egg into a baby's diet at an early age.

Are there any side-effects and risk associated with this study?

Potentially, your child may develop a sensitivity to the powder. If this happens, you should contact the research team who will provide advice and give you the option of returning to the Allergy Clinic for ongoing management. The study will not place your child at a greater risk of food allergy than that for the general population, as the study guideline for both groups of children is consistent with the current recommendations of the Australian Society for Clinical Immunology and Allergy (ASCI) on infant feeding.

The skin prick tests may cause some discomfort in some children, but they are performed daily as a routine procedure in the hospital and most children do not find them painful. The visit at 12 months will require a small blood sample to be taken (2mls) which can be painful and cause bruising. To reduce this, a cream (topical anaesthetic) will be applied to numb the skin first, unless you request otherwise.

Other information

All data obtained will be kept on your child's hospital record, which only authorised members of hospital staff will be able to see. The data will not be released to others without your permission. Data will then be transferred from the hospital system to a secure database, but will be kept anonymous by being assigned a number. Data may be published in medical journals and/or at medical conferences, but only anonymous group data will be reported. The data will be securely kept for at least 15 years as required by NSW and Federal Law, and then destroyed according to hospital guidelines.

Participation in this project is voluntary and if you decide not to take part or decide to withdraw at any time this will not otherwise affect your child's care at the Hospital.

If you have any questions about the conduct of this study, please do not hesitate to discuss them with the study investigator, A/Professor Dianne Campbell. She can be contacted on (02) 9845 3418 or by email: beat@chw.edu.au .

This project has been approved by The Children's Hospital at Westmead Ethics Committee. If you have any concerns about the conduct of this study, please do not hesitate to contact the Research Ethics Manager, Secretary of the Ethics Committee (02 9845 3017) and quote approval number 10/CHW/4.

This Information Sheet is for you to keep. We will also give you a copy of the signed consent form.