WHAT ARE THE POSSIBLE RISKS OF TAKING PART IN THIS STUDY?

Medical procedures and sample collections sometimes cause side effects. Your baby may have none or some side effects. If your baby has any new or unusual symptoms talk with the study researchers, who will also be looking out for side effects. Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

WILL YOU BE USING INFORMATION COLLECTED AS PART OF ORIGINS?

Yes, we will request permission from you to access the questionnaire information you have provided to the ORIGINS project. We will ask your consent to examine the blood and breast milk samples that were collected from you and your child. We will also request permission from you to share the information we collect as part of the BENEFIT Trial with the ORIGINS data and biobanks.

DO I HAVE TO TAKE PART IN THIS RESEARCH STUDY?

Participation in any research study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part in the BENEFIT Trial and later change your mind, you are free to withdraw from the study at any stage. Should you choose to withdraw, please notify Dr Debbie Palmer on phone 9408 3113 or email Debbie.Palmer@telethonkids.org.au. The information and samples that you provide will continue to be kept securely and used for the purpose of the study unless you request for them to be disposed of.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your partner, nor your relationship with the Joondalup Health Campus.

WHO ARE THE RESEARCHERS LEADING THIS STUDY?

The Chief Investigators on this BENEFIT Trial are Professor Susan Prescott and Dr Debbie Palmer from the University of Western Australia and Telethon Kids Institute.

WHO TO CONTACT IF YOU HAVE ANY CONCERNS ABOUT THE ORGANISATION OR RUNNING OF THE STUDY?

The ethical aspects of this study have been approved by the Joondalup Health Campus Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in a research project, please contact JHC Executive Office on (08) 9400 9404. Any complaint you make will be investigated by an independent party, treated in confidence, and you will be informed of the outcome.

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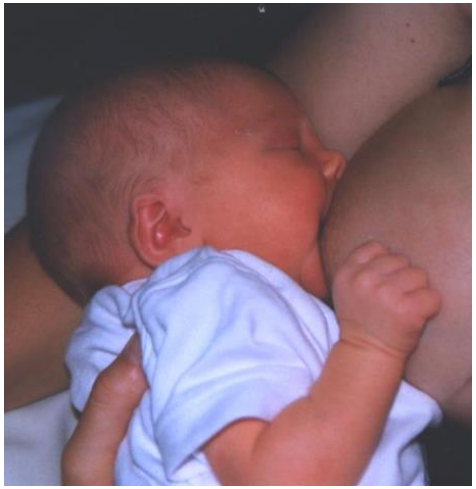
THE ORIGINS PROJECT

Breastfeeding and Eating Nuts and Eggs For Infant Tolerance (BENEFIT) Trial



ANY QUESTIONS?

If at any time during the BENEFIT Trial you have any questions, please ring our office on 9408 3113 or email the BENEFIT Trial Chief Investigator, Dr Debbie Palmer at Debbie.Palmer@telethonkids.org.au

TELETHON KIDS INSTITUTE
Discover. Prevent. Cure.

THE UNIVERSITY OF WESTERN AUSTRALIA

Joondalup Health Campus
Part of Ramsay Health Care

Version 3 19th January 2019

WHAT IS THE BENEFIT TRIAL?

You are invited to participate in a study that aims to reduce the risk of food allergies in children. By 1 year of age, 10% (1 in every 10) babies will develop a food allergy. We now know that regular consumption of traditionally allergenic (causing allergic reactions) foods, like egg and peanut, in solid foods can help to reduce food allergies. However this is too late for some babies, who have an allergic reaction to a food the first time they eat it after commencing solids.

We think that breastfeeding could be the ideal opportunity to prevent food allergy prior to solid food introduction. We know that the food proteins in allergenic foods, like egg and peanut, can be detected in breast milk. The more egg that is eaten by a breastfeeding mother, the higher the amount of egg protein that can be measured in her breast milk. However we do not know whether more or less eggs (or peanuts) eaten by a breastfeeding mother will help to reduce the risk of her baby developing food allergies.

The aim of the BENEFIT Trial is to answer the question of whether the amount of eggs and peanuts a mother eats during breastfeeding has an influence on her baby's food allergy development.

HOW MANY PARTICIPANTS?

108 women and their babies.

WHO CAN PARTICIPATE IN THE BENEFIT TRIAL?

- **Women whose babies have at least two family members (mother, father or siblings) with medically diagnosed allergic disease (asthma, eczema, hay-fever or food allergy). Babies who have at least two family members with allergic disease have a higher risk of developing food allergy.**
- **Women who are planning to breastfeed for at least 6 months.**
- **Women who do not have an egg or peanut allergy.**
- **Women who are not participating in the SYMBA Study.**

WHAT WILL HAPPEN TO MY INFORMATION COLLECTED IN THIS STUDY?

All information gathered about you, such as personal and health details, and questionnaire answers, will be treated with confidence. No information that could identify you or your child will be released to any person not associated directly with the study. All members of the BENEFIT Trial team are required to sign confidentiality agreements and are committed to protecting the confidentiality and privacy of data and biological samples.

In exceptional circumstances, disclosure of your health information can be required by law, for example, as a result of a court order. Such requests are rare; however, we have an obligation to inform you of this possibility.

The results from the study may eventually be published in medical journals or at professional meetings, but you will not be identified in any way.

WHAT DOES MY PARTICIPATION INVOLVE?

In addition to your participation in the ORIGINS Project, we would ask you to follow the BENEFIT Trial dietary advice you are given about amounts of eggs and peanuts to eat per week from birth until your baby is 6 months of age.

Eating eggs and peanuts

- You will be randomly assigned (like tossing a coin) to one of two groups. Neither you nor the research team will be able to choose which group you are in. The amounts of eggs and peanuts will be either:
  Group 1: 6 eggs and 60 peanuts (= 2 handfuls) per week
  Group 2: up to 2 eggs and up to 20 peanuts per week
- You will be able to include all forms of egg and peanut, and egg and peanut containing foods, towards your weekly target of egg and peanut ingestion. You will be provided with a conversion table showing the amount present in common egg or peanut foods, for example peanut butter, or egg in quiche, or in baked goods.
- You will be provided with a supply of both peanuts and peanut butter to reduce costs of participation in this trial. Due to the reduced shelf-life of eggs you will need to purchase these yourself.

Telephone calls

We will telephone you for approximately 10 minutes when your baby is 1, 2 and 5 months of age to ask how you are going with eating the eggs and peanuts. In addition we will gather information about any illnesses or health problems you are having. You will also be asked about your baby's feeding and any symptoms of allergies. We will also telephone you for approximately 10 minutes when your baby is 9 months of age to ask about any allergic reactions your baby may have had after commencing solid foods.

Attending Appointments and Sample Collection

In addition to the appointments and sample collections as part of your participation in the ORIGINS Project, as detailed in the ORIGINS Participant Information Booklet, your participation in the BENEFIT Trial would also involve two additional appointments when your baby is 3-4 and 6 months of age. At these additional two appointments:

- We will ask how you are going with eating the eggs and peanuts and we will gather information about any illnesses or health problems you are having.
- You will be asked about your baby's feeding and any symptoms of allergies. Your baby will have a full skin assessment to check for signs of eczema.
- A sample of your baby's blood (5mL = 1 teaspoon) will be collected.
- These visits will be at no cost to you, nor will you be paid. All the tests and medical care required as part of the study will be provided to you free of charge.