THE SYMBA STUDY: PROMOTING GUT HEALTH (SYMBIOSIS) FOR ALLERGY PREVENTION

ANY QUESTIONS?

If at any time during the SYMBA study you have any questions, please ring our office on 9408 3113 or email the SYMBA Study team at SYMBAStudy@telethonkids.org.au

Community SYMBA Study Version 4 23rd March 2018

WHAT IS THE SYMBA STUDY?

You are invited to participate in a study that aims to reduce the risk of allergic disease in children by improving the balance of 'healthy bacteria' in the gut, using a high fibre prebiotic supplement in pregnancy and while breastfeeding. We are focused on investigating the factors that could influence the development of allergies in childhood. We see pregnancy as the ultimate window of opportunity to prevent allergic disease. Allergic diseases are common in Australian children. By 1 year of age, more than 25% (1 in every 4) of all babies will suffer from eczema and 10% (1 in every 10) will develop a food allergy. We now know that a baby's immune system develops even before birth, and that the mother's diet and her environment in pregnancy can have an important influence.

The aim of the SYMBA Study is to examine if a high fibre prebiotic supplement, taken during pregnancy and while breastfeeding, will reduce the risk of allergic disease in children, with potential benefit to other aspects of health, growth and development. Prebiotics are natural, dietary products (fibre) and are very unlikely to cause any illness. They occur naturally in foods such as whole grains, vegetables and legumes, and may be associated with minor short-term changes in bowel habits. These food ingredients are called 'prebiotics' because they are digested by gut bacteria, but are different from 'probiotics' which are the actual 'friendly bacteria'.

WHO CAN PARTICIPATE IN THE SYMBA STUDY?

- Pregnant women whose babies have an immediate family member (mother, father or sibling) with a history of one or more allergies (asthma, hayfever, eczema and/or food allergy).
- Women who have not smoked during their pregnancy.
- Women who do not regularly consume prebiotic supplements.
- Women who do not have a diagnosed cow's milk allergy or lactose intolerance.

HOW MANY PARTICIPANTS?

652 women and their babies will be followed up over 5 years.

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 and 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 SYMBA Study team are required to sign confidentiality agreements and are committed to protecting the confidentiality and privacy of data and biological samples.

In very rare 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 take a study powder during pregnancy and until your child is 6 months of age. The study powder will be either a prebiotic supplement powder or a placebo powder (an inactive powder containing a carbohydrate food ingredient only that looks like the prebiotic powder).

Taking the study powder

• You will be randomly assigned (like tossing a coin) to one of two groups. One group will be given a prebiotic powder and the other group will be given a placebo powder. You will be asked to add the powder to your food or drinks from about 18 weeks gestation (mid-pregnancy). We will ask you to take the powder once daily until your baby is 6 months of age. The powder can be added to drinks (like juice or smoothies) or mixed into cold food like yoghurt. Neither you nor the research team will be able to choose which group you are in and you will not know which group you are in until after the study is completed.

• For the remainder of your pregnancy and the first 6 months of breastfeeding, we ask that you do not regularly consume prebiotic supplements other than the study powder that we provide to you. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

Telephone calls

We will telephone you for approximately 10 minutes when you are 24 and 32 weeks pregnant to ask how you are going on the study powder. In addition we will gather information about any illnesses or health problems you are having.

We will also telephone you for approximately 10 minutes when your baby is aged 1, 2 and 5 months of age. During these phone calls we will ask how you are going on the study powder 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.

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 SYMBA study would also involve one additional appointment at 28 weeks pregnancy and two additional appointments when your baby is 3-4 and 6 months of age. At these additional appointments:

• We will ask how you are going on the study powder 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 at 3-4 and 6 months.

• At 28 weeks pregnancy and 3-4 months, a sample of your blood (30mL,1.5 tablespoons) will be collected.

• At 28 weeks pregnancy we will ask you to provide a stool sample

• These visits will be at no cost to you, nor will you be paid. All the study powder, tests and medical care required as part of the study will be provided to you free of charge.

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

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

Prebiotics are natural dietary products (fibre) and are very unlikely to cause any illness. They can be found in foods such as whole grains, vegetables and legumes, and may be associated with minor transient changes in bowel habits, in some people. Allergies to prebiotics have been reported, but these are very rare.

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, breast milk and stool 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 SYMBA study 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 and later change your mind, you are free to withdraw from the study at any stage. Should you choose to withdraw, 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 SYMBA Study are Professor Susan Prescott and Dr Debbie Palmer from the University of Western Australia. The Co-Investigators include researchers from the Telethon Kids Institute, The University of Western Australia and clinicians from the Joondalup Health Campus.

WHO SHOULD I CONTACT IF I 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.