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iFAAM: EuroPrevall birth cohort follow-up study

PARTICIPANT INFORMATION SHEET: FOOD CHALLENGES (Parents/Guardians)

Your child is participating in iFAAM (Integrated Approaches to Food Allergen and Allergy Risk Management), the follow-up to the EuroPrevall birth cohort study. We hope this study will help us gain more understanding of why children develop allergies and asthma. Information of this kind may help us develop strategies to prevent the development of allergies and asthma in the future.

You have received this information sheet because your child has symptoms or signs suggestive of food allergy. Before you decide to participate in this part of the study it is important for you to understand why the research is being done and what it will involve.

- Part 1 tells you the purpose of this part of the study and what will happen to your children if they take part.
- Part 2 gives you more detailed information about how this part of the study will be undertaken.

Please read the following information carefully and discuss it with others if you wish. Please do not hesitate to contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

PART 1

What is the purpose of the follow-up study?

In the follow up iFAAM study, we plan to reassess all children from the Europrevall study at school age to understand how older children are affected by food allergy and how this relates to other allergies such as asthma.

The study aims to find answers to the following questions:

- Why do so many children develop allergies while others do not?
- What happens to food allergies that started in early childhood, do they disappear in school-age or persist?
- Can we predict allergies in school-age with genetic information or environmental data we have from infancy and preschool age?
- How do dietary habits influence food allergy?
- Which new allergies develop in school age?

Why has my child been chosen to take part in this part of the study?

Your child has been chosen because they took part in the iFAAM study and they now have symptoms or signs suggestive of food allergy.

What will happen to me and my child if I take part?

Your child will come into the NIHR Wellcome Trust Clinical Research Facility in Southampton for the food challenge. It will usually involve two visits with a gap of 2-6 days between them. Each will last 6-8 hours. Further details can be found under "*What do we have to do?*".

What do we have to do?

You and your child will be asked to attend the NIHR Wellcome Trust Clinical Research Facility in Southampton on two separate days. On each day your child will be given a standard challenge meal but on one of the days it will contain the food suspected to be causing the allergy. The presence of the suspect food will be hidden so neither you, your child nor the paediatrician will know which of the two days the suspect food will be given.

The challenge procedure is the same on each of the two days and will be as follows. The standard meal is split up into increasing doses with the first dose being very small. After each dose your child is carefully observed. The challenge will be stopped if a reaction occurs and your child will be given treatment to control the symptoms. If no reaction is seen the challenge continues until all the doses are taken. Your child will be observed in the clinic for 2 hours after the challenge is stopped whether that is due to a reaction or not.

If your child may be allergic to other foods, it may be necessary for them to attend on additional days, one for each suspect food to test for allergy.

If your child has asthma, we would ask them to try not to use their blue asthma reliever inhaler (eg salbutamol, ventolin, bricanyl, terbutaline) during the 4 hours before the visit. We would also ask you not to use any antihistamines (eg loratidine, clarityn, cetirizine, zirtec, piriton) in the 3 days before the visit.

Allergy skin prick testing: if we were not able to undertake skin prick testing at the previous home/centre visit, we would like to undertake this at the beginning of the first challenge day. This is done to determine whether your child's immune system reacts to certain food, animal or pollen allergens. This is a safe, routine investigation that we use in allergy clinics.

Blood test: if we were not able to obtain a blood sample at the previous home/centre visit and you agree, we would like to collect a small amount (about a tablespoon) of your child's blood after their skin has been numbed with anaesthetic cream. This would be on either day 1 or day 2 of the food challenge. Half of the blood will be used for the analysis of antibodies against allergens (e.g. foods, pollens) to predict allergies, the other half is for genetic testing to search for genes predisposing for or protecting from allergies and asthma.

Questionnaire: we would ask you to complete a short food allergy quality of life questionnaire at the start of day 1. This tells us about how children and their families find living with food allergies.

What are the possible disadvantages and risks of taking part?

There may be a little discomfort associated with skin prick testing. When blood is drawn, you and/or your child will feel a little discomfort. A small bruise might form in that area or very rarely someone may faint. With a positive food challenge, expected reactions are itching, stomach upset, hives, or worsening of eczema. Severe reactions, such as anaphylaxis (allergic shock) are very rare. All challenges are closely supervised by an experienced paediatrician and medications are kept readily at hand to treat any reaction. Prior to attending the food challenge your child will need to stop taking their blue asthma reliever inhaler and/or antihistamine for the specified period. This could present a risk, but if you feel the use of the inhaler or antihistamine is necessary during this period then the appointment can be re-arranged.

What are the possible benefits of taking part?

Your child will be evaluated for food allergy. This can be difficult to detect and accurately diagnose. We may be able to rule out one or more food allergies so that your child can eat these foods without concerns. If we diagnose a food allergy we can provide advice as to how it can be managed. Taking part in this part of the study will have no negative influence on the regular care of your child. Your travel expenses will be reimbursed and your GP will be informed about the allergy and test results. Your participation in this part of the study will help scientists and physicians to develop diagnostic tools and preventive strategies for dealing with food allergies.

Do I have to take part?

No, you and your child do not have to take part in this part of the study. It is completely voluntary and you do not have to take part in every aspect of the study if you do not want to. If you do decide to participate, you will be given this information sheet to keep and asked to sign a consent form. You will receive a copy of the signed consent form. You are free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect your medical care.

Will my taking part in the study be kept confidential?

Yes. All the information about you and your childs participation in this study will be kept confidential.

This completes PART 1 of the Information Sheet. PART 2 will give you further information about the study.

PART 2

What if there is a problem?

If you have a concern about any aspect of this part of the study, you should ask to speak with the researchers who will do their best to answer your questions (see contacts for further information below). If you still have questions or concerns, you can contact Research and Development, University Hospitals Southampton NHS Foundation Trust (023 8120 5078). In the very unlikely event that something does go wrong and you are harmed during this part of the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation against University Hospital Southampton NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

The personal information collected in this part of the study will be kept confidential. The data we collect from you will not be labelled with your or your child's personal details and will be stored securely. Data collected during this part of the study may be shared with our research collaborators; however they will not know who the information belongs to as your name and address will only be kept at University Hospital Southampton NHS Foundation Trust. Only the study personnel will have access to your child's personal details. The sponsor of the study (University Hospital Southampton NHS Foundation Trust) may also wish to access the records as part of their monitoring of ongoing research. You will not be individually identified in any reports or publications resulting from the study. We will keep your data on file for use in future studies approved by the Research Ethics Committee.

What will happen to the blood samples.

The part of the blood samples to be analysed for antibodies (against allergy-causing proteins such as foods or pollen) will be sent to and stored frozen at *Amsterdam Academic Medical Center, Department of Experimental Immunology (led by Dr. Ronald van Ree), Meibergdreef 9, Amsterdam 1105 AZ, The Netherlands*.

Blood used for genetic testing will be shipped to and stored frozen at *Charité – Universitätsmedizin Berlin, Department of Paediatric Pulmonology and Immunology (Prof.Kirsten Beyer), Augustenburger Platz 1, 13353 Berlin, Germany*.

All samples will be identified by your child's study number only and not with their name or **any** other personal information.

Who will have access to my health records?

Senior Investigators on this project will need to look at your health records to ensure safe conduct of the study procedures.

Involvement of the General Practitioner

We would like your permission to notify your child's General Practitioner (GP) of your and your child's participation in this study. With your permission we will send your GP the results of your child's allergy tests as they may be useful for their future medical care. We would not send your GP any other results from the study.

What will happen to the results of the research study?

We aim to publish the results of the study in medical journals so that other doctors and researchers can make use of them. This is likely to be accompanied by an article in the press. It will not be possible to identify any individuals involved in this study from these published results.

Who is organising and funding the research?

The researchers at the University of Southampton are organising and carrying out this study. The study is being funded by the European Union within the project *Integrated Approaches to Food Allergen and Allergy Risk Management* (iFAAM, grant agreement no. 312147).

Who has reviewed the study?

This study was given a favourable ethical opinion by the NRES Committee South Central - Hampshire B.

How long do I have to decide whether I should take part?

Your and your child's decision to participate in this study is entirely voluntary. You should take as much time as you need to make your decision.

What happens at the end of the study?

If we find that your child has food allergy, we will write to your GP with suggestions for how to manage the condition. Where necessary we will suggest a referral to the local paediatric allergy or asthma clinic. If your child does not have a food allergy we will take no further action that is not part of the main EuroPrevall follow-up study.

CONTACT FOR FURTHER INFORMATION, QUESTIONS OR CONCERNS

Professor Graham Roberts on 023 8120 6160, email iFAAM@southampton.ac.uk or visit www.southampton.ac.uk/iFAAM.

Thank you for taking time to read this information sheet.