



## A longitudinal investigation of skin barrier development from birth and the validation of early predictors of eczema risk: the Skin Testing for Atopic eczema Risk (STAR) study

Research team: Simon Danby, John Chittock, Alison Cooke, Tina Lavender and Michael Cork

*We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you and your baby. Please feel free to discuss this information with your family, a healthcare professional or STAR study team member. Thank you for taking the time to read this document.*

### What are we trying to find out?

Following birth our skin takes a number of years to mature before it gives us the protection we need from our environment. Without adequate protection our bodies are exposed to irritants, allergens and bacteria that cause a range of skin problems including eczema/dermatitis. Developing eczema as a child increases the risk of developing other conditions such as hayfever, asthma and food allergy. We would like to look carefully at the skin of a group of 150 babies during their first year of life to see how it matures, and identify whether we can predict early on which babies are most at risk of developing eczema. The early identification of these high-risk babies opens up the opportunity to stop them from developing eczema in the first place, and could potentially prevent the development of hayfever, asthma and food allergy too.

### Why have I been invited?

You are being invited to join because you will shortly become, or have just become, a mother who lives in the local Sheffield community. All healthy newborn babies born after 37 weeks of pregnancy at the Jessop Wing Maternity Hospital are eligible to take part.

### Do I have to take part?

No. It is up to you whether you and your baby would like to take part. Consider the information in this sheet to help you decide, and feel free to contact us if you have any questions. If you decide to take part you are free to withdraw at any time, without giving a reason. Your decision will not affect the standard of care that you or your baby receives, now or in the future.

### What will happen if I take part?

If you agree to join the study you will be asked to sign a consent form on behalf of you and your baby, and you will be given a copy of this information sheet and the consent form to keep.

We will perform a number of harmless procedures on your baby's skin. The first of these will be conducted on the maternity ward before you go home. The same procedures will be performed at your home at 4 weeks and around 12 months after your baby's birth. We will arrange a convenient time with you during the day for us to visit you. We will arrange to call you approximately 6 months following your baby's birth to ask questions about you and how you have cared for your baby's skin in general. The questions will take no more than ten minutes to complete.

In addition to this we will ask you to keep a daily diary (first month) and a weekly diary (months 2-6) on how you care for your baby's skin and whether you observe any skin problems, such as red rashes. At the end of the study we will ask you to complete a questionnaire about your opinions of the study.

We would also like to ask some of you to take part in two telephone interviews lasting 30-60 minutes each, at a time of your choice. This will be to find out more about your views on early diagnosis of skin conditions, potential treatments and how acceptable the ways of testing your baby's skin are to you. There are no right or wrong answers, we just want to try and understand your views and experiences. Only 20 people are required for the interviews so not everyone will be chosen.

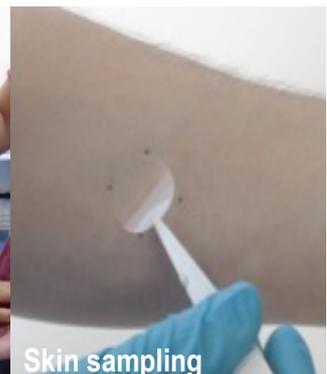
#### Will I need to change the way I look after my baby's skin?

No. We simply want to follow the normal development of your baby's skin following birth. This means that you can decide how you care for your baby's skin.

#### What procedures will we do?

We will collect information in several ways. None of the assessments will harm your baby:

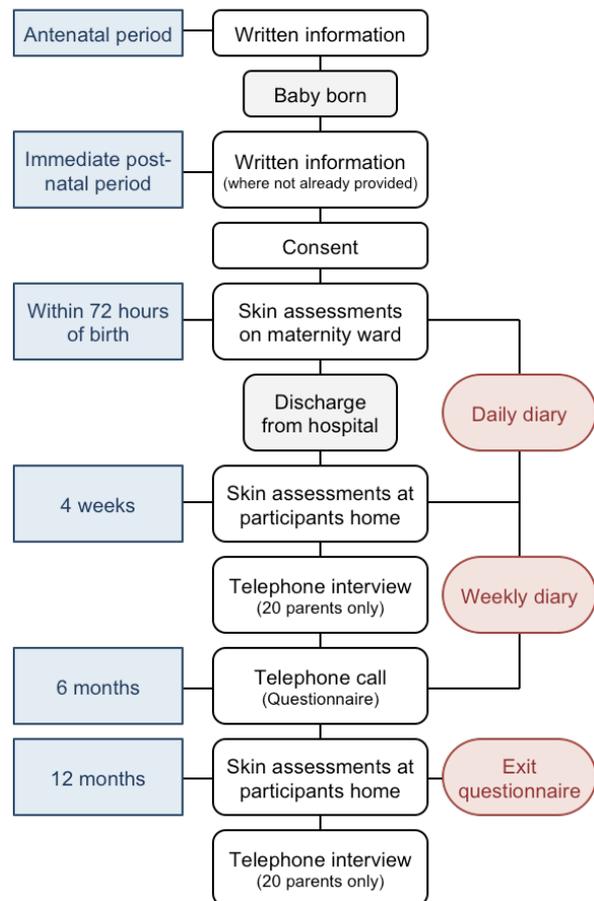
1. *Visual assessment.* This will involve looking at the condition of your baby's skin. If your baby shows signs of eczema, this will involve grading how severe the eczema is.
2. *FTIR Spectroscopy.* This will involve placing the assessment tool briefly in contact with your baby's skin on the arm and thigh. The tool uses the same light as found in your TV remote control, and gathers information on skin structure. We will wipe the skin with a mild baby wipe prior to collecting some measurements.



3. *Transepidermal Water Loss.* This will involve placing a probe on your baby's skin for approximately 60 seconds on the arm and thigh. The probe measures the rate of water loss from your baby's skin, which indicates how well it acts as a barrier.

4. *Collection of skin samples.* This will involve collecting surface skin samples using small sticky-tape discs to collect only the very top skin cells that are already dead and about to be shed naturally by the body. The procedure is painless and will not leave a permanent mark. You will be given the opportunity to apply these discs to your own skin to experience the procedure for yourself. We will analyse the discs in the laboratory to look at the natural enzymes within your baby's skin.

#### The Participant Pathway



5. *Microbial swab*. We will simply rub your baby's skin gently with a wet sterile swab to collect a sample of the microbes on your baby's skin surface. These will be stored at the University of Sheffield Medical School for future research on the development of the skin microflora from birth.
6. *Buccal swab / saliva sample*. We will collect a sample of your baby's saliva using a buccal swab. This sample will be used to analyse your baby's genes (DNA) to assess their inherited risk of eczema.
7. *Questionnaire*. It is important for us to find out about your skin, what you think about the study, your baby's skin care product use, care of your baby's skin in general and your home environment. We will therefore ask you to complete two questionnaires throughout the study (one conducted over the phone at 6 months).
8. *Diary*. We will ask you to keep a daily diary during the first month, and a weekly diary throughout months 2-6, on how you care for your baby's skin and whether you observe any skin problems, such as red rashes.
9. *Telephone Interviews (for 20 participants only)*. With your consent you may be asked to take part in two telephone interviews; once when your baby is between 2 and 6 months old, and again at 12 months. This is to find out more about your views of baby skin care and the study, such as early diagnosis of skin conditions, potential treatments and how acceptable the ways of testing your baby's skin are to you, which can take place at a time of your choice. The interviews will be recorded, and anonymised direct quotes will be used in study reports. In order to arrange the interviews we will need to pass your name and contact details on to Dr Alison Cooke, a Midwife Researcher and STAR team member at The University of Manchester, who will be conducting the interviews. Where necessary each of the interviews can be conducted in 2 parts.

#### What will happen if my child develops a skin problem whilst taking part?

We will not offer treatment for your baby's skin. If you have any concerns you should seek medical attention and advice from your usual GP. Taking part in this study will not affect any treatment your baby may need. All that we ask is that you keep us informed about any skin conditions or allergies that your baby develops.

#### What are the possible benefits of taking part?

There are no direct benefits to you or your baby for taking part in this study. However, by taking part you will help us to better understand how a baby's skin develops over the first year. We may also be able to identify early indicators of eczema risk. In future, by identifying which babies are at risk of developing eczema, we may be able to help parents to take steps to prevent the condition arising. Upon completion of the 4-week and 12 month assessment visits you will be given a £40 Amazon gift voucher to say thank you for the time you have given up (a total of £80 in Amazon gift vouchers). An additional £20 Amazon gift voucher will be given to the participant's taking part in the interviews.

#### Are there any risks?

We do not anticipate any risks, as all of the procedures involved in this study do not cause any harm.

#### What will happen to any samples I give?

Your samples will be treated as a gift. They will be kept in a secure location within The University of Sheffield Medical School. Access to your samples, which will not be labeled with personal identifiable information, will be restricted to members of our research team only. Your skin and saliva samples will be kept for a maximum of 5 years and DNA samples (derived from your saliva) will be kept for a maximum of 25 years following the end of the study. These are held under the custodianship of the Principle Investigator and the University of Sheffield, so that they may be available to support future studies. Should you choose to withdraw from the study we will destroy your sample upon request.

#### Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you and your baby will be kept strictly confidential. Any information about you or your baby that leaves the hospital will have the name and address deleted, so that you and your baby cannot be recognised by it. This includes data that are transmitted

electronically. Each of you will be allocated a unique study number, which will be used for recording demographic and study data. All electronic data will be stored on a secure server, managed by the University of Sheffield, and will be identifiable only by the unique study number. Personal contact details will be recorded separately on paper and stored in a locked filing cabinet in a locked research office. Any information included in written reports/presentations will not identify you or your baby by name. Where necessary we will use a false name. Only the members of the research team will have access to you or your baby's identifiable data.

If you consent to take part in the study with your baby, some parts of your medical record, your baby's medical record, and the data collected for the study may be looked at by authorised persons from the Sheffield Teaching Hospitals NHS Foundation Trust and/or regulatory authorities to check that the study is being carried out correctly. Your name, or your baby's name however, will not be disclosed outside of the hospital.

#### What will happen to the results of the research study?

We will use information from the study to write scientific reports but they will not include any information that makes it possible for you to be identified. We will distribute a summary of our findings to all participants at the completion of the study.

#### Who is organising and funding the research?

This study is organised by researchers at The University of Sheffield and The University of Manchester. The study is funded by the Leo Foundation.

#### Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your and your baby's safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by North West – Preston Research Ethics Committee (Ref: 16/NW/0848), and Sheffield Teaching Hospitals NHS Trust (Ref: STH 19479).

#### What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions (Tel: 07834392439). If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Services Team (The Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF; telephone 0114 271 2400).

In the event that something does go wrong and you are harmed during the research due to someone's negligence then you may have grounds for legal action and compensation, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

#### What next?

If you would like to take part please contact:

**STAR Research Midwife: Hilary Rosser**

**Contact Number: 0114 2268514**

To know more about the study or discuss anything in this information sheet please contact the study team:

Department of Infection, Immunity & Cardiovascular Disease, The University of Sheffield Medical School, Beech Hill Road, Sheffield S10 2RX.

Telephone: 07834392439, Email: [starstudy@sheffield.ac.uk](mailto:starstudy@sheffield.ac.uk), Website [www.shef.ac.uk/iicd/dermatology](http://www.shef.ac.uk/iicd/dermatology)



## The Skin Testing for Atopic eczema Risk (STAR) study

Research Team: Simon Danby, John Chittock, Alison Cooke, Tina Lavender and Michael Cork

Participant Identification Number for this study: \_\_\_\_\_

Please initial box

1. I confirm that I have read the information sheet dated 21/10/16 (version 1) for the above study. I have had the opportunity to consider the information, ask questions and I have had these answered satisfactorily.

2. I give permission for my baby and I to undergo the procedures listed in this document

3. I understand that my and my baby's participation are voluntary and that we are free to withdraw at any time without giving any reason, without my, or my baby's, medical care or legal rights being affected. If I withdraw midway through the study, or I lose the capacity to reaffirm my consent, I give permission for my anonymised study data / samples to be retained and used by the study team.

4. I understand that relevant sections of my, and my baby's study records and medical notes may be looked at by individuals from the NHS Trust, the study team, or by regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my, and my baby's, records.

5. I agree to taking part in two telephone interviews lasting 30-60 minutes

6. I agree to my conversation being audio recorded during the telephone interviews

7. I agree to my anonymised quotations taken from the telephone interviews being used in scientific reports and conference presentations

8. I give consent for my baby's genomic DNA to be collected (by buccal swab) and tested as part of this study.

9. I understand that the anonymised information collected about me and my baby, the microbial skin swab samples and my baby's genomic DNA may be used to support other research in the future, and may be shared with other researchers

10. I give permission for my baby's anonymised DNA sample to be stored securely at The

University of Sheffield for up to 25 years after completion of the study

11. I agree to my personal information being kept securely by the study team for up to 5 years following the end of the study so that I may be contacted again about further research studies related to STAR

12. I, and my baby, agree to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature