

NIHR Bristol Nutrition Biomedical Research Unit

Study Information Sheet

Study title: Feeding and Autoimmunity in Down's syndrome Evaluation Study (FADES)

Dear Parent(s)

Congratulations on the birth of your baby!

Thank you for showing interest in our research study, and for asking for more information.

We would like to follow up your baby's early life looking at any feeding problems you might encounter, any infections your child has and whether these are associated with the development of conditions more common in children with Down's syndrome.

What is the purpose of the study?

This study will look at early feeding in babies and children with Down's Syndrome and see how feeding and early infections may be related to the increased risk children with Down's syndrome have of developing thyroid, coeliac disease (which causes gut problems) and diabetes. These are all known as autoimmune conditions.

Do we have to take part in this study?

The simple answer is no. If you do not wish to take part, it will in no way affect the care you and your child receives from any of your doctors.

What will I be asked to do if I take part?

You will be asked to fill in a questionnaire online (or a paper version depending on your preference) which mainly asks questions about your baby's birth history, medical history and early feeding. It also contains some questions about your family history and briefly about your medical history. This initial questionnaire will take around 30 minutes to complete. There are further questionnaires about your baby's medical history and feeding at six and twelve months these are shorter and will take around 20 minutes to complete. We will then send out an annual, short questionnaire about your child's health, which takes about 10 minutes to complete every year until your child is 5 years old.

The Bristol Nutrition Biomedical Research Unit (BRU) is funded by the National Institute for Health Research (NIHR) and is a partnership between University Hospitals Bristol NHS Trust and the University of Bristol.

We would also like to collect a sample of stool (poo) from you (the mother) and from your baby, as well as urine from your baby at six and twelve months and yearly thereafter if possible. We will also ask you to use a special tiny brush, to brush the inside of your baby's cheek. All of these samples can all be collected at home.

Every baby born in the UK has a small sample of blood taken from a heel prick as part of their new born screening and with your permission we will also analyse this spot of blood.

Finally we would like to collect small samples of blood from your child using a special heel/finger prick sample collector which causes minimal discomfort. The first sample we will arrange to be done during one of your baby's routine health checks. We would also like to collect bloods samples at six and twelve months and yearly thereafter we will advise you on how these can be taken at your child's routine appointments with health care professionals, when your child would normally be having routine screening bloods. If however you would prefer to take these samples yourself at home once you have seen the first sample being taken we will advise you on how you could do this. All the samples can then be sent with any paper questionnaires back to Bristol in the supplied pre-paid packages. **Your child should not need additional hospital attendances.**

We understand that this study involves considerable time and input from participants and if for any reason, you miss a sample/questionnaire we would still like your child to continue in the study as your contribution will still be important.

Below is a chart showing the timeline for questionnaires and sample collection for your baby.

Months of age	0*Baseline	7	12	24	36	48	60
Combined feeding and medical questionnaire	X	X	X				
Medical questionnaire				X	X	X	X
Mouth swab	X						
Stool (poo) sample	X	X	X	X	X	X	X
Urine sample	X		X	X	X	X	X
Heel or finger prick blood sample.	X	X	X	X	X	X	X

What will happen to the samples that are provided?

We will be analysing your child's samples to see if we can find any common findings which might explain why babies with Down's Syndrome might develop autoimmune conditions. The mouth swab will be used to look at your baby's genes (little packets of information within your cells) particularly those that we know may be associated with autoimmune conditions. We will look at your stool and your baby's stool (poo) to see the natural bacteria that live within the gut. The urine sample will help us to know which babies may be developing diabetes although we expect that very few babies will develop diabetes during the 5 years that they are in the study. The blood samples will be used to look for antibodies which are associated with autoimmune conditions.

What are the possible disadvantages and risks of taking part?

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We do not believe there to be any risks. Your child might find the heel / finger prick tests a little uncomfortable but it only lasts a minute or so and there will only be seven of these over five years. We do understand that this is a considerable commitment in terms of being part of an on-going study as you will have additional papers to fill in and samples to be collected from your child that families with a child with Down's syndrome do not normally have to do.

What are the possible benefits in taking part?

This study is designed to try and find out what difficulties babies and children with Down's Syndrome have with feeding and infections. We want to reduce the risk of these problems and develop new treatments to help with feeding. We also hope we will increase our knowledge of why children with Down's syndrome are at increased risk of developing problems with their hormones and gut known as "autoimmune conditions". These include thyroid or coeliac disease and diabetes.

Whilst our findings may not directly help your baby they will hopefully benefit children born with Down's Syndrome in the future. From the findings of this study we hope that we will be able to develop an intervention to help with feeding babies born with Down's Syndrome. We also hope the study will enable us to provide parents and carers of children with Down's syndrome with more information regarding feeding and autoimmune conditions.

Will details on my child in this study be kept confidential?

All data collected in this study will be maintained and stored in strict accordance with the data protection regulations. All information that is collected about you and your child during the course of the research will be kept strictly confidential. All members of the study team will have a duty of confidentiality to you and your child as research participants.

We keep the information we collect about your child and the results from any samples collected separate from your child's personal details and we can only link this information together with a secure code. Only authorised people working on the study will have access to your child's information.

With your consent we will inform your child's GP and community paediatrician that your child is participating in the study and will send them a factsheet explaining what will be involved, we will also inform your GP. We will also contact key members of your child's health care team with your consent to arrange blood sampling. They will not have access to any of the information that is collected about your child during the course of the research; we will only contact them if any of the results are significant for your child's current or future health.

What happens to the data and samples collected when this research study is finished?

We will keep the data and samples for 15 years and then destroy them securely unless you have chosen to consent for the data and / or samples to be stored for use in future ethically approved studies in this area of research. If this is the case we will give you the option to be re-contacted in order that you can provide your consent again if you so wish to do so.

Who is organizing and funding the research?

The study is sponsored by the University of Bristol and is funded by the National Institute of Health Research, Bristol Biomedical Research Unit in Nutrition. The study is being conducted as part of a Clinical PhD in Child Health.

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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 safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NRES committee (South West Central Bristol Research Ethics Committee). This study has also been reviewed by the executive board of the Bristol Biomedical Research Unit, the University of Bristol Research and Enterprise development team and the University Hospitals Bristol Research and Development team.

What if something goes wrong?

The researchers do not anticipate that taking part in this study could cause any harm to your child. In the eventuality that its negligence does cause injury to your child, the University holds Public Liability insurance. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact details below). If you remain unhappy and wish to complain formally, you can do this by contacting the hospitals Patient Support and Complaints Team (contact details below).

Will I be informed of the results of the study?

If you would like to be updated regarding the progress of the study we can arrange to send you regular updates via email. At the end of the study we will provide you with a summary of the findings and copies of any publications that you would like to receive.

What do I do now?

Thank you for considering taking part in this research. We will contact you either by email or telephone depending on your preference and will answer any questions you may have. Once you have had an opportunity to ask any questions, if you are interested in your child taking part, please fill in the consent forms which we will send to you in the post with a copy of this information sheet. Keep one copy for your own records and send the other back to us in the stamped addressed envelope provided.

If you have any questions regarding the study please call the FADES research team on +44 (0)117 342 1756 or email fades-study@bristol.ac.uk.

If you have concerns about any aspect of the way you have been approached or treated during the course of this study you may wish to contact the hospital's Patient Support and Complaints Team on 0117 342 3604, email pals@uhbristol.nhs.uk or write to Patient Support & Complaints Team, Trust Headquarters, University Hospitals Bristol, Marlborough Street, Bristol, BS1 3NU

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