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

Submission date	Recruitment status	[_] Prospectively registered
23/07/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/04/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/01/2023	Genetic Diseases	

Plain English Summary

Background and study aims
Children with Down's Syndrome (DS) have an increased risk of autoimmune conditions where the body's immune system attacks its own cells, such as thyroid problems, diabetes and coeliac disease. There is some evidence that prolonged breastfeeding protects against diabetes and coeliac disease. We think that in infants with DS early feeding practices may be related to the development of autoimmunity. Children with DS may have difficulties with breastfeeding, leading to rapid introduction of formula feeds. We aim to study the association between early infant feeding, infections and the development of autoimmunity.

Who can participate?
Babies less than 8 months old with DS.

What does the study involve?
Parents will be asked to complete questionnaires at the start of the study detailing family history, birth history, weight, medical problems and early feeding. They will have further feeding questionnaires at 7 and 12 months, and medical questionnaires annually until the age of 5 years. Samples will be collected at the start of the study including faeces, a brushing from the infant's cheek for genotyping (looking at their DNA), a blood sample to look at autoantibody production (antibodies which act against their own cells), and a urine specimen to detect development of diabetes. Further stool, urine and blood samples are collected at 6 months, 12 months and yearly thereafter until 5 years of age.

What are the possible benefits and risks of participating?
There are not any risks to taking part in the study. The heel/finger prick tests may cause some minor discomfort but there will only be seven of these over a five-year period. The participants will have additional questionnaires and samples to collect which families with a child with DS do not normally have to do. Apart from the initial blood test these samples can all be done at home if the parents feel able to do this or can be taken at the child's routine appointments and will not require any additional hospital attendances. We wish to try and find out what difficulties babies with DS have with feeding and infections and how this may contribute to the development of autoimmunity. Whilst our findings may not directly help the participants they may benefit children born with DS in the future and we are therefore relying on the research participants

goodwill. From this study we hope to go on and do a further study to develop an intervention to help with feeding in babies born with DS. We also hope the study will increase knowledge in this area for the parents of children with DS as well as those that care for them.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
July 2014 to January 2022

Who is funding the study?
NIHR Biomedical Research Unit in nutrition, diet and lifestyle at University Hospitals Bristol NHS Foundation Trust and University of Bristol (UK)

Who is the main contact?
Dr Georgina Williams

Contact information

Type(s)
Scientific

Contact name
Dr Georgina Williams

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16735

Study information

Scientific Title
Feeding and Autoimmunity in Down's syndrome Evaluation Study (FADES): an observational cohort study

Acronym
FADES

Study hypothesis
This study will aim to establish the feasibility of developing a cohort from across the UK of children with Down's Syndrome in whom we can study how feeding and early infections may be related to the increased risk children with Down's Syndrome have of developing thyroid, coeliac disease and diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West – Central Bristol, 23/04/2014, ref: 14/fw0030

Study design
Non-randomised; Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Condition
Topic: Children; Subtopic: All Diagnoses; Disease: Down's syndrome, autoimmunity

Interventions
Phase 1: Samples will be collected by parents on the ward from their baby's nappy. The samples need to be 'fresh' (passed within an hour) and they will need to take three samples from the same 'dirty nappy' (i.e. from the same stool). In order to acquire a 'fresh' stool we will ask parents to check their baby's nappy regularly within one hour after a feed as babies tend to have a pronounced gastro-colic reflex. – I don't think this needs to be included as not part of the main study

Phase 2: Parents will be asked to complete questionnaires at baseline detailing family history, birth history, weight, medical problems and early feeding. They will have further feeding questionnaires to complete at 7 months and 12 months, and medical questionnaires annually until the age of 5 years. Samples would be collected at baseline including faeces to look at gut microbiome, a brushing from the infant's cheek for genotyping, a blood sample to look at development of auto-antibody production (specifically autoantibodies to insulin, GAD, IA-2 and

ZnT8R/W, which are all associated with type 1 diabetes, anti-BSA antibody, antibodies to tissue transglutaminase (Tg), antibodies to thyroid peroxidase (TPO), antibodies to gastric H+/K+ ATPase 4A), and a urine specimen for urinary c peptide to detect development of diabetes. Further stool, urine and blood samples will be collected at 6 and 12 months and once a year thereafter until 5 years of age.

Intervention Type
Other

Primary outcome measure
As a feasibility study the primary outcome is to have established a cohort of children with Down’ s syndrome in which we have been able to record early feeding practice and obtain samples from which we can study the development and natural history of autoimmunity in relation to feeding and the gut microbiome.

Secondary outcome measures
Comparing babies with Down's syndrome who have breastfed with those that have not, we will be studying:
1. Whether they have significant differences in autoantibody status
2. Whether they have differences in the diversity of their gut microbiomes
We would also be investigating the correlation between levels of anti-BSA antibodies and correlate with autoantibody positivity in all participants who had been exposed to cow's milk protein.

Overall study start date
01/07/2014

Overall study end date
01/01/2022

Eligibility

Participant inclusion criteria
Babies recruited antenatally or in the first 8 months of life born with Down's syndrome (three copies of chromosome 21) as confirmed by karyotype after birth

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Participant exclusion criteria

1. Babies with Down's syndrome who have a child protection plan or who are no longer with their birth mother
2. Babies with Down's syndrome over 8 months of age
3. Babies with Down's syndrome in whom the parents do not speak English

Recruitment start date
01/07/2014

Recruitment end date
01/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The National Institute for Health Research Biomedical Research Unit in Nutrition, Diet and Lifestyle
University Hospitals Bristol NHS Foundation Trust
University of Bristol
Bristol
United Kingdom
BS2 8AE

Study participating centre
Over 200 sites
United Kingdom
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Sponsor information

Organisation
University of Bristol

Sponsor details
Research Enterprise and Development
Senate House
Tyndall Avenue
Clifton

England
United Kingdom
BS8 1TH

Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Biomedical Research Unit (BRU) (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2022	17/01/2023	Yes	No