ISRCTN00424386 https://doi.org/10.1186/ISRCTN00424386

Feasibility randomised controlled trial: probiotics and milk formula to prevent allergic disease

Submission date 13/02/2008	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/02/2008	**Overall study status** Stopped	
Last Edited 10/04/2012	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Aziz Sheikh

Contact details
Division of Community Health Sciences: GP Section
The University of Edinburgh
Levinson House
20 West Richmond Street
Edinburgh
United Kingdom
EH8 9DX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CZG/2/277

Study information

Scientific Title
Investigating the effectiveness of primary prevention strategies using extensively hydrolysed milk formula and probiotic supplements to prevent allergic disease in high risk infants: pilot factorial randomised controlled trial

Study objectives
The primary aim of this pilot study is to test the feasibility of administering an extensively hydrolysed milk formula, with either a placebo probiotic or probiotic, to mothers with infants at high risk of atopic disease in Scotland and compare the likely uptake and effectiveness of these interventions using a factorial randomised controlled trial. This study will inform a definitive large-scale multi-centre double blind placebo randomised controlled trial.

As of 10/04/2012, the anticipated end date of trial was updated from 31/12/2008 to 31/10/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending from the Lothian Ethics Committee as of 13/02/2008.

Study design
Feasibility study: 2 x 2 factorial randomised controlled design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Atopic disease: asthma, atopic dermatitis, allergic rhinitis or food allergy

Interventions
1. Probiotic or placebo probiotic: one sachet of probiotic to be mixed with 1 ml of water, taken once daily
2. Normal milk formula or extensively hydrolysed milk formula: study formula to be taken as needed

The total duration of treatment will be six months, and the total duration of follow-up for all treatment arms will be six months. The three and six month assessments will take up to one hour.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Milk formula, probiotic

Primary outcome measure
1. Recruitment rate, i.e., what proportion of those invited agree to participate, measured at three months
2. Retention rate, i.e., what proportion of those enrolled complete the study, measured at the end of the study
3. Acceptability of interventions to mothers, measured at three and six month assessment
4. Parental reports of acceptability of interventions to infants, measured at three and six month assessment
5. Incidence and severity of atopic eczema at 3 and 6 months
6. Acceptability to midwives, health workers and paediatric nurse, measured at nine months

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/04/2008

Completion date
31/10/2008

Reason abandoned (if study stopped)
"Objectives no longer viable"

Eligibility

Key inclusion criteria
1. Infants at high risk of atopy as judged by the mother, father or sibling having an allergic disease (asthma, allergic rhinitis, atopic dermatitis and food allergy)
2. Booked to give birth at the Royal Infirmary, Edinburgh

Participant type(s)
Patient

Age group
Child

Sex

Both

Target number of participants
36

Key exclusion criteria
1. Do not give informed consent
2. Multiple pregnancy
3. Delivering prior to 37 weeks gestation

Date of first enrolment
01/04/2008

Date of final enrolment
31/10/2008

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Division of Community Health Sciences: GP Section
Edinburgh
United Kingdom
EH8 9DX

Sponsor information

Organisation
Chief Scientist Office (UK)

Sponsor details
St Andrews House
Edinburgh
United Kingdom
ED1 3DG

Sponsor type
Government

Website
http://www.sehd.scot.nhs.uk/cso/

ROR
https://ror.org/01bw7zm61

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (UK) (ref: CZG/2/277)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration