

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

Not provided at time of registration.

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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

United Kingdom

Scotland

Study participating centre

Division of Community Health Sciences: GP Section

Edinburgh

United Kingdom

EH8 9DX

Sponsor information

Organisation

Chief Scientist Office (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration