ISRCTN33578711 https://doi.org/10.1186/ISRCTN33578711

The influence of Neocate or cow's milk protein-based formula on acid and non-acid gastro-oesophageal reflux in infants

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 07/12/2015	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Michael Thomson

Contact details
Department of Paediatric Gastroenterology
Royal Free Hampstead NHS Trust
Pond Street
Hampstead
London
United Kingdom
NW3 2QG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0256124183

Study information

Scientific Title
The influence of Neocate or cow's milk protein-based formula on acid and non-acid gastro-oesophageal reflux in infants

Study objectives
Is Neocate a simple safe alternative to cow's milk protein-based formula for infants suspected of having gastro-oesophageal reflux associated oesophagitis?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
Neonatal Diseases: Gastro-oesophageal reflux associated oesophagitis

Interventions
Double blind study of Neocate versus cow's milk protein-based formula

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Service outcome development

Secondary outcome measures
Not provided at time of registration

Overall study start date
29/04/2003

Completion date
30/09/2003

Eligibility

Key inclusion criteria
20 patients

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
20

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
29/04/2003

Date of final enrolment
30/09/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free Hampstead NHS Trust
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Royal Free Hampstead NHS Trust (UK)

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