

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/12/2015	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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