# The influence of Neocate or cow's milk proteinbased formula on acid and non-acid gastrooesophageal reflux in infants

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

## 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

Protocol serial number 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

#### Study type(s)

**Not Specified** 

### 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(s)

Service outcome development

### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

30/09/2003

## **Eligibility**

#### Key inclusion criteria

20 patients

#### Participant type(s)

#### **Patient**

## Healthy volunteers allowed

No

### Age group

Neonate

#### Sex

All

### 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

**United Kingdom** 

England

## Study participating centre Royal Free Hampstead NHS Trust

London United Kingdom NW3 2QG

## Sponsor information

## Organisation

Department of Health

## Funder(s)

#### Funder type

Hospital/treatment centre

## Funder Name

The Royal Free Hampstead NHS Trust (UK)

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes