

Cysteine requirements for preterm infants

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 04/11/2008	Condition category Neonatal Diseases	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NTR245

Study information

Scientific Title

To determine the requirement of cysteine in preterm infants with different gestational ages and post-natal age

Study objectives

1. Cysteine is an essential amino acid for newborn preterm infants
2. Cysteine requirements change rapidly with postnatal age
3. The change in cysteine requirement with age is based upon cystathionase activity
4. Intestinal cystathionase activity is of major importance for the conversion of methionine to cysteine

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre, randomised, single blind, active controlled, crossover trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Premature infants, glutathione (GSH) deficiency

Interventions

Infants receive a test diet with graded amounts of cystine for 32 hours.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cystine

Primary outcome(s)

1. Fractional oxidation of ^{13}C -phenylalanine
2. Whole body flux of ^{13}C -phenylalanine

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/06/2006

Eligibility**Key inclusion criteria**

1. Infants born with a gestational age of 26 - 29 weeks will be studied at a post-conceptual age of 30 - 32 weeks and at a post-conceptual age of 35 - 37 weeks
2. Infants born at a gestational age of 32 - 34 weeks will also be studied at a post-conceptual age of 35 - 37 weeks

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Congenital metabolic disease
2. Congenital anomalies
3. Gastrointestinal diseases

Date of first enrolment

01/11/2004

Date of final enrolment

01/06/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Erasmus Medical Centre

Rotterdam

Netherlands

3000 CB

Sponsor information**Organisation**

Sophia Foundation For Scientific Research (SSWO) (Netherlands)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Sophia Children's Hospital Fund (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration