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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
1. Fractional oxidation of 13C-phenylalanine
2. Whole body flux of 13C-phenylalanine

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2004

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-conceptional age of 30 - 32 weeks and at a post-conceptional age of 35 - 37 weeks
2. Infants born at a gestational age of 32 - 34 weeks will also be studied at a post-conceptional age of 35 - 37 weeks

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
80

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)

Sponsor details
P.O. Box 2060
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Sponsor type
Research organisation

Website
http://www.vriendensophia.nl/?/sophia_home/welkom

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sophia Children's Hospital Fund (The Netherlands)

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