

# Cysteine requirements for preterm infants

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/11/2008	<b>Condition category</b> 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

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### Contact details

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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  $^{13}\text{C}$ -phenylalanine
2. Whole body flux of  $^{13}\text{C}$ -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-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

**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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info@vriendensophia.nl

### **Sponsor type**

Research organisation

### **Website**

[http://www.vriendensophia.nl/?/sophia\\_home/welkom](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