

# Glutathione Metabolism in Neonates

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/02/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr F W J te Braake

**Contact details**  
Erasmus Medical Center  
Sophia Children's Hospital  
Room Sk-2210  
P.O. Box 2060  
Rotterdam  
Netherlands  
3000 CB  
+31 (0)10 463 6015  
f.tebraake@erasmusmc.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
NTR243

# Study information

## Scientific Title

Glutathione kinetics and oxidative stress in preterm infants

## Study objectives

1. Low glutathione (GSH) status in preterm and sick term infants is due to a high utilisation rate of GSH rather than a low synthetic capacity
2. Current feeding strategies in preterm and sick term infants fail to supply enough substrate for an adequate GSH production rate

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from the local medical ethics committee

## Study design

Randomised double-blind active controlled parallel group 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

Glutathione (GSH) deficiency

## Interventions

Preterm infants are resuscitated with different oxygen concentrations at birth

## Intervention Type

Drug

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Glutathione

## Primary outcome measure

Glutathione synthesis rate, measured at day 2 post-natal

### **Secondary outcome measures**

1. Concentration of oxidative stress markers, Apgar Score, oxygen saturation and heart rate in first 20 minutes after birth, measured on day 1 and day 7
2. Mortality
3. The incidence of bronchopulmonary dysplasia

### **Overall study start date**

11/08/2005

### **Completion date**

11/08/2007

## **Eligibility**

### **Key inclusion criteria**

Preterm infants with birth weights less than 1500 g and term infants. Infants in both groups should have arterial catheters for the purpose of obtaining blood samples.

### **Participant type(s)**

Patient

### **Age group**

Neonate

### **Sex**

Both

### **Target number of participants**

80

### **Total final enrolment**

20

### **Key exclusion criteria**

1. Known congenital abnormalities
2. Chromosome defects
3. Metabolic disease
4. Endocrine, renal, or hepatic disorder

### **Date of first enrolment**

11/08/2005

### **Date of final enrolment**

11/08/2007

## **Locations**

### **Countries of recruitment**

Netherlands

**Study participating centre**  
**Erasmus Medical Center**  
Rotterdam  
Netherlands  
3000 CB

## Sponsor information

### Organisation

Sophia Foundation For Scientific Research (SSWO) (Netherlands)

### Sponsor details

P.O. Box 2060  
Rotterdam  
Netherlands  
3000 CB  
+31 (0)10 463 6079  
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

Charity

### Funder Name

Friends of the Sophia Foundation (Stichting Vrienden van het Sophia) (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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2009	18/02/2021	Yes	No