

Glutathione Metabolism in Neonates

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/12/2005	Overall study status Completed	☐ Protocol
Last Edited 18/02/2021	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised double-blind active controlled parallel group trial

Study type(s)

Treatment

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(s)

Glutathione synthesis rate, measured at day 2 post-natal

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

Funder(s)

Funder type

Charity

Funder Name

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

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?
Results article	results	01/11/2009	18/02/2021	Yes	No