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Glutathione Metabolism in Neonates

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

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

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