Glutathione Metabolism in Neonates.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27445

Source
Nationaal Trial Register

Brief title
N/A

Sponsors and support

Primary sponsor: Sophia Foundation For Scientific Research (SSWO)
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Intervention

Outcome measures

Primary outcome

Glutathione synthesis rate.

Secondary outcome

1. Concentration of oxidative stress markers, Apgar Score, oxygen saturation and heart rate in first 20 minutes after birth;

2. Mortality;

3. The incidence of bronchopulmonary dysplasia.

Study description

Background summary

Preterm infants are subjected to increased formation of reactive oxygen species and have reduced antioxidant defenses. The resulting oxidative stress is thought to play an important role in mortality and incidence of neonatal diseases like bronchopulmonary dysplasia.
Birth is accompanied by sudden exposure to increased oxygen pressure, which results in increased formation of reactive oxygen species. In term infants, resuscitation at birth with 100% oxygen leads to increased oxidative stress and mortality. Thus, the current recommendations are to start resuscitation of all infants with 21% oxygen. However, it seems that 21% oxygen is not enough for preterm infants.
Therefore, we will determine safety, efficacy and oxidative stress of the use of different oxygen concentrations with preterm at birth.

Study objective

Resuscitation after birth with 30% oxygen reduces oxidative stress and is safe in preterm infants.

Study design

1. Glutathione synthesis: at day 2 postnatal;

2. Concentration of oxidative stress markers on day 1 and day 7;

3. Apgar Score, oxygen saturation and heart rate in first 20 minutes after birth.

Intervention

Preterm infants are resuscitated with different oxygen concentrations at birth.

Contacts

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Eligibility criteria

Inclusion criteria

Preterm infants with gestational age < 32 weeks.

Exclusion criteria

Known congenital abnormalities, chromosome defects, metabolic disease, and endocrine, renal, or hepatic disorder.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-08-2005
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL206

Register	ID
NTR-old	NTR243
Other	: N/A
ISRCTN	ISRCTN82896385

Study results

Summary results
N/A