High versus low initial oxygen to improve the breathing effort of preterm infants at birth

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Interventional

Summary

ID

NL-OMON46752

Source
ToetsingOnline

Brief title
IMProving Respiration with Oxygen Evaluation study (IMPROvE study)

Condition

- Respiratory disorders congenital
- Neonatal and perinatal conditions

Synonym
Prematurity, preterm birth

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Chiesi Farmaceutici,Chiesi Farmaceutici SpA

Intervention

Keyword: breathing effort, initial, oxygen, preterm

Outcome measures

Primary outcome

The main study parameter is respiratory effort in the first 5 minutes after

birth expressed as average respiratory minute volume.

Secondary outcome

Secondary parameters are inspired tidal volumes, rate of rise to maximum tidal

volumes, percentage of recruitment breaths with tidal volumes above 8 ml/kg and

duration of hypoxia and hyperoxia during stabilisation and plasma levels of

markers of oxidative stress (8-iso-prostaglandin F2α).

Study description

Background summary

Although most preterm infants breathe at birth, their respiratory drive is weak and often insufficient to aerate their lungs and establish gas exchange. Extra oxygen is often needed to correct hypoxia, but could then lead to hyperoxia. The optimal concentration of oxygen to start stabilisation after birth is still not clear, as both hypoxia and hyperoxia can attribute to organ injury. To reduce the risk of hyperoxia, currently an initial low oxygen concentration is recommended during stabilisation, accepting the risk of a period of hypoxia. However, hypoxia inhibits respiratory drive in preterm infants. Starting with a higher level of oxygen could lead to a shorter duration of hypoxia and thus stimulate breathing effort of preterm infants, but increase the risk for hyperoxia. Improving the respiratory drive decreases the need for additional ventilation or intubation and mechanical ventilation.

Study objective

The objective of this study is to compare the direct effect of the administration of an initial FiO2 of 1.0 versus 0.3 on respiratory effort during stabilisation of preterm infants in the first 5 minutes after birth.

After evaluation of the initial settings, FiO2 will be titrated based on the oxygen saturation target range.

Study design

A multi-center randomized controlled trial.

Intervention

Based on randomization, stabilisation after birth will be started with a FiO2 of either 1.0 or 0.3, after which FiO2 will be titrated based on the oxygen saturation target range. In both groups, other interventions needed for stabilisation and thereafter will be given conform standard care.

Study burden and risks

Most preterm infants breathe insufficiently at birth and develop respiratory distress syndrome. Previous studies demonstrated that achieving adequate oxygenation directly after birth is difficult and additional oxygen supplementation is required in most cases. The only difference between groups in the proposed study is the initial FiO2 during stabilisation after birth.
After the initial setting, FiO2 will be titrated up in the low FiO2-group and titrated down in the high FiO2-group following target ranges for oxygen saturation.
In preterm infants at birth both hypoxia and hyperoxia needs to be avoided as they are both associated to increased risk for organ injury. Currently the starting FiO2 is low (0.3), increasing the risk for hypoxia in the first minutes, insufficient respiratory drive and an increased risk for additional ventilation or intubation and mechanical ventilation. When starting with a high FiO2 (1.0), the risk for hypoxia will decrease, but could increase the risk for hyperoxia. However, in both groups, the goal is to obtain normoxia in the newborn as soon as possible after birth. To minimize risks for hypoxia and hyperoxia in both groups FiO2 will be titrated based on oxygen saturations guided by target ranges defined in this protocol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm infants of 24-30 weeks of gestation will be randomized to start stabilisation after birth with a FiO2 of either 1.0 or 0.3.

Exclusion criteria

Congenital abnormality or condition that might have an adverse effect on breathing or ventilation, if these conditions are not already diagnosed before birth, including: congenital diaphragmatic hernia, trachea-oesophageal fistula or cyanotic heart disease.

Study design

Design

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

Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	01-12-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-05-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL62897.058.17