Pilot study: Randomised controlled trial of interface use during stabilisation of preterm infants in the delivery room

Published: 17-04-2009
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The aim of this study is to test the hypothesis that using nasal tube as interface during resuscitation/stabilisation of preterm infants at birth is more effective compared to mask.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Interventional

Summary

ID

NL-OMON32567

Source
ToetsingOnline

Brief title
MOUNTAIN trial (Mask Or Use of Nasal Tube As INterface)

Condition

- Neonatal respiratory disorders

Synonym
respiratory distress of the preterm infant at birth

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: mask, nasal tube, preterm infant, resuscitation

Outcome measures

Primary outcome

The need for intubation in the first 24 hours after birth

Secondary outcome

Any complication caused by use of the interface, bronchopulmonary dysplasia at

36 weeks of gestation, incidence of air leak, incidence of IVH, mortality

before discharge from hospital.

Study description

Background summary

During resuscitation of preterm infants at birth it is essential to deliver adequate tidal volume and a consistent level of positive end-expiratory pressure (PEEP). The most frequent used devices are the self-inflating bag or a mechanical T-piece device, both with a mask as interface.1 Studies2, 3 have shown that inadequate sealing between face and mask often leads to inappropriate and inconsistent peak inspiratory pressures (PIP) and PEEP, which may be harmful and leads to need for intubation.

There is limited data that the use of prongs or a nasopharyngeal tube to deliver efficient PIP and PEEP during resuscitation alleviates dependence on sufficient sealing by a facemask, providing that both the mouth and the other nostril are closed.

Study objective

The aim of this study is to test the hypothesis that using nasal tube as interface during resuscitation/stabilisation of preterm infants at birth is more effective compared to mask.

Study design

This is a single-center non-blinded randomized controlled trial.

Intervention

Resuscitation will be with the allocated device either the nasal tube or the mask. In both groups the Neopuff, a mechanical resuscitator with a T-piece, will be used. Other than allocation of the type of interface, the technique of resuscitation will not be affected in any way by this study. All other resuscitative measures (e.g. intubation, external cardiac massage, administration of oxygen and other drugs) will be at the discretion of the staff involved, following international guidelines.
Criteria for intubation in the delivery room and in the NICU are protocolized and will be followed as strictly as possible.

Study burden and risks

none

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

preterm infants, gestational age range 25-29 weeks (more than 25 weeks and not more than 28 weeks and 6 days).

Exclusion criteria

antenatal diagnosed congenital anomalies of the cardial or respiratory system or anomalies incompatible with survival.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2009
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	17-04-2009
Application type:	First submission

Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	28-09-2009
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27370
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL25699.058.08
OMON	NL-OMON27370