PEEP resuscitation in preterm neonates, a double blinded, randomized, controlled trial comparing 5cmH2O and 8cmH2O PEEP.

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In this multicenter trial we compare resuscitation of preterm neonates with either 5 cm H2O PEEP or 8 cmH2O PEEP. We think resuscitation with 8 cmH2O PEEP results in a better outcome compared to resuscitation with 5 cmH2O PEEP.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON35483

Source
ToetsingOnline

Brief title
Resuscitation with different PEEP levels in preterm neonates

Condition

- Neonatal and perinatal conditions
- Neonatal respiratory disorders

Synonym
care for neonates, lung expandure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Intubation, Morbidity, Mortality, Resuscitation

Outcome measures

Primary outcome

Our primary outcome is defined as the need for intubation within 72 hours after birth.

Secondary outcome

Secondary outcomes are the duration of mechanical ventilation, need of surfactant treatment, bronchopulmonary dysplasia, cranial ultrasound abnormalities, retinopathy of prematurity, necrotizing enterocolitis, air leaks and mortality.

Study description

Background summary

The use of positive end expiratory pressure (PEEP) is a recent development in the resuscitation of newborn neonates. PEEP creates a positive pressure in the alveoli during exhaling, preventing the neonatal lungs from collapse. Furthermore, neonatal lungs are fluid filled after delivery. PEEP *pushes* fluid in intracellular cavity. Recently, a study showed that resuscitation with a nasopharyngeal tube, controlled inflation and a consistent PIP and PEEP should be preferred compared to conventional balloon and mask resuscitation. Neonates needed less intubation <72 hours post partum, less mechanical ventilation, less surfactant and developed less bronchopulmonay dysplasia (BPD). In lamb studies, resuscitation with 8 cmH2O PEEP was significantly superior to resuscitation with 4 cmH2O PEEP.

Study objective

In this multicenter trial we compare resuscitation of preterm neonates with either 5 cm H2O PEEP or 8 cmH2O PEEP. We think resuscitation with 8 cmH2O PEEP results in a better outcome compared to resuscitation with 5 cmH2O PEEP.

Study design

A double-blinded, randomized controlled multicenter trial.

Intervention

We compare breathing assistance or resuscitation in the neonate with either 5 cmH2O PEEP or 8 cmH2O PEEP.

Study burden and risks

The neonates in the study will not be exposed to extra tests compared to normal neonates in the neonatal intensive care unit (NICU). Infants in the study receive the high care of the NICU. It is not possible to perform this study on adults as they cannot be compared to neonatal lungs which are fluid filled and are surfactant deficient just after birth. Our hypothesis is that subjects have a chance of receiving better resuscitation compared to infants in current resuscitation practices. Increased PEEP could theoretically give an increased risk of pneumothoraces. However, previous studies showed a tendency, not significant, to less pneumothoraces.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm infants with a gestational age of < 30 0/7 weeks

Exclusion criteria

any major congenital malformations at birth.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	240
Type:	Actual

Medical products/devices used

Generic name:	neoPuff
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-12-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-05-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL22217.068.10