Randomized crossover comparison of mask leak between facemask and nasal mask ventilation; a pilot study.

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To compare the occurrence of significant mask leak when using a nasal mask versus a facemask in preterm infants needing positive pressure ventilation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Observational non invasive

Summary

ID

NL-OMON37897

Source
ToetsingOnline

Brief title
Testing Interfaces in Neonates. (TIN)

Condition

- Neonatal respiratory disorders

Synonym
mask ventilation

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: Facemask, Leak, Nasal mask, Neonatology

Outcome measures

Primary outcome

Percentage of inflations with a large amount (> 60%) of leak.

Secondary outcome

The administered tidal volumes and the incidence of obstruction.

Study description

Background summary

The most frequent used interface during resuscitation with the self-inflating bag or a mechanical T-piece device, is the facemask. Studies have shown that inadequate sealing between face and mask often leads to inappropriate and inconsistent peak inspiratory pressures (PIP) and positive end expiratory pressure (PEEP), which may be harmful. Effective resuscitation at birth may improve clinical outcome in preterm infants.
Segedin et al. showed that manual ventilation can be better performed via the nasal route. It has been shown that delivery of positive pressure ventilation though the nasal route via nasal prongs is favourable in terms of outcome (chest compressions and intubation) compared to delivery through a face mask. There however is limited evidence that other device who use the nasal route, deliver efficient PIP and PEEP during resuscitation by decreasing the amount of leak. Examples of these devices are the nasal canula and the nasal mask. The applicability of these devices will alleviate the dependence on sufficient sealing by a facemask, providing that both the mouth and the other nostril are closed during resuscitation.
The nasal mask is often used in the unit as interface to deliver non-invasive respiratory support (continuous positive airway pressure (CPAP) or nasal intermittent mandatory ventilation). In other units it is used to deliver respiratory support in preterm infants at birth. However, so far the effectiveness of the nasal mask has not been tested and compared with the facial mask. To create rationale for a larger clinical trial we wish to perform a small pilot study comparing the effectiveness of a nasal mask with the standard facemask in preterm infants needing positive pressure ventilation.

Study objective

To compare the occurrence of significant mask leak when using a nasal mask versus a facemask in preterm infants needing positive pressure ventilation.

Study design

This is a non-blinded randomized controlled crossover trial which will be performed in the neonatal unit in the Leiden University Medical Center, Leiden, the Netherlands.

Study burden and risks

It is standard as part of the intubation procedure that infants are mask ventilated right after sedation and prior to intubation. Two T-piece resuscitation devices will be prepared, one with the allocated device and one with face mask as interface. In this way a fast switch to the other interface can be performed and takes only a few seconds. The allocated interface will be used for one minute after which the resuscitator switches to the other device. In any case, if the infant*s condition deteriorates, the resuscitator will immediately switch to standard procedure and use the mask as interface.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm born infants requiring non-emergency intubation during admission on the Neonatal Intensive Care Unit.

Exclusion criteria

Preterm born infants who need immediate intubation in resuscitation setting or who have facial, laryngeal of pharyngeal malformations.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2012
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Nasal mask

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-08-2012
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL39751.058.12