Propofol during Minimal Invasive Surfactant Evaluation Study

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The primary objective of this study is to compare the level of stress and comfort of preterm infants when sedation is given during the MIST procedure compared to no sedation.

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

Summary

ID

NL-OMON40970

Source
ToetsingOnline

Brief title
PROMISES

Condition

- Respiratory disorders congenital
- Neonatal and perinatal conditions

Synonym
Respiratory Distress Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Neonatologie
Source(s) of monetary or material Support: Chiesi Farmaceutici,Chiesi Farmaceutici SpA en Den Dulk Moerman LUF subsidie

Intervention

Keyword: Comfort, MIST, Propofol, Surfactant

Outcome measures

Primary outcome

The main study parameter is the comfort-neo score, the primary endpoint is the percentage of infants with a comfort-neo score below 14 during the procedure.

Secondary outcome

Secondary study parameters are;

- Occurrence of positive pressure ventilation during and right after the procedure;
- Occurrence of intubation needed during the procedure and within 24 hours;
- Number of attempts of endotracheal insertion of angiocatheter;
- Duration of the total procedure (from start inserting laryngoscope, until exit angiocatheter);
- Complications occurring during the procedure: desaturation < 85%, hypotension (mean below gestational age), bradycardia < 80 bpm, nasal hemorrhage;
- Other complications: pneumothorax, pulmonary haemorrhage, resuscitation;
- Heart rate and blood pressure before, during and 5 minutes after the procedure.

Study description

Background summary

Premature infants who are at risk of developing Respiratory Distress Syndrome (RDS) require surfactant therapy to reduce the risk op pneumothorax and

neonatal death. In the traditional method, surfactant is instilled after endotracheal intubation and when the infant is mechanically ventilated, but minimally invasive surfactant therapy (MIST) is promising, in which surfactant is administered via an endotracheal catheter to a spontaneously breathing infant who then remains on non invasive ventilation (CPAP). In this way, possible disadvantageous effects of intubation and mechanical ventilation can be avoided. Although infants are routinely sedated for endotracheal intubation, it is unclear whether during a MIST procedure sedation should be given.

Study objective

The primary objective of this study is to compare the level of stress and comfort of preterm infants when sedation is given during the MIST procedure compared to no sedation.

Study design

A single blind randomized trial.

Intervention

The administration of propofol (1 mg/kg) versus no sedation. In both groups standard comfort care will be given, which consists of administering sucrose 24% in the cheek pouch of the infant together with containing the infant with his pacifier two minutes before the intervention starts, and containing the infant during the procedure.

Study burden and risks

When randomized to the use of sedation, both risk and benefit are possible. Propofol is the standard sedative used in the unit, there is a low risk for side effects such as apnea, bradycardia and hypotension. The risk is minimal as we will be using a lower dose then standardly used for endotracheal intubation (1 mg/kg instead of 2.5 mg/kg). Also, all standard precautions will be taken for immediate counteract/treatment of the possible side effects of propofol. The possible benefits in the sedation group are more comfort during the procedure and a higher chance to a successful procedure at the first attempt.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm infants (26-37 weeks of gestation) needing surfactant therapy for RDS according to local criteria (FiO2 > 30% and PEEP > 8).

Exclusion criteria

Imminent need for intubation because of respiratory distress, apnea or persistent acidosis. Infants who suffer from pneumothorax or pulmonary hemorrhage.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2015
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	08-12-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	25-03-2015
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

No registrations found.

In other registers

Register	ID
CCMO	NL50864.058.14