# Propofol during Minimal Invasive Surfactant Evaluation Study

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON28656

**Source**
NTR

**Brief title**
PROMISES

**Health condition**

RDS
surfactant
non-invasive

### Sponsors and support

**Primary sponsor:** Leiden University Medical Centre
**Source(s) of monetary or material Support:** LUF/Den Dulk Moerman Fonds, Chiesi Pharmaceutical

### Intervention

### 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 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 haemorrhage

Other complications: pneumothorax, pulmonary haemorrhage, resuscitation

Heart rate and blood pressure before, during and 5 minutes after the procedure.

## Study description

### Background summary

Rationale: Premature infants who are at risk of developing Respiratory Distress Syndrome (RDS) require surfactant therapy to reduce the risk of 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 a 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.
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 blinded randomized trial.

Study population: Preterm infants (26-37 weeks of gestation) needing surfactant therapy for RDS according to the local criteria (FiO2 >30% O2 and PEEP 8) will be randomized.
Intervention: The administration of propofol (1 mg/kg) or 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.

Main study parameters/endpoints: 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 apnoea, bradycardia and hypotension. This risk is minimal as we will be using a lower dose than 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. However, because these risks exist in usual care (the supervising neonatologist decides whether or not an infant receives sedation for MIST), there is no additional risk when participating in this study. 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.

## Study objective

There is consensus that an endotracheal intubation procedure should be performed while the infant is adequately sedated. However, whether sedation should be given during the minimal invasive surfactant procedure is still unclear. So far, no studies concerning sedation during this procedure have been performed. Although it has been argued that the laryngoscopy is highly uncomfortable, no studies in preterm infants have been performed. In contrast, experience from the feasibility studies suggests that the MIST procedure is generally well tolerated without any premedication. However, in these studies the comfort of the preterm infants during the procedure has not been objectively evaluated. In addition, it is unclear whether sedation will contribute to the risk for a failed procedure by compromising the infant¡¯s respiratory drive, but it can also increase the chance for an uneventful, smooth and successful procedure.

## Study design

one hour before MIST procedure - discharge

## Intervention

The investigational treatment is the use of sedation during the MIST procedure. Hereby propofol will be used, which is standardly used in our NICU for intubation. The risk for side effects will be minimal as for the MIST procedure a lower dose will be used than the standard dose used for endotracheal intubation (1 mg/kg instead of 2.5 mg/kg). 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.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Preterm infants (26-37 weeks of gestation) needing surfactant therapy for RDS according to the local criteria (FiO2 >30% and PEEP ¡Ý 8) can be randomized for sedation or no sedation.

## Exclusion criteria

Excluded are infants where there is imminent need of intubation because of respiratory distress, apnoea or persistent acidosis. Infants who suffer from a pneumothorax or pulmonary haemorrhage will also be excluded.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |

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|---|---|
| Masking: | Single blinded (masking used) |
| Control: | N/A , unknown |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 05-01-2015 |
| Enrollment: | 78 |
| Type: | Actual |

## Ethics review

Positive opinion

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|---|---|
| Date: | 18-12-2014 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL4765 |
| NTR-old | NTR5010 |
| Other | METC LUMC : P14263 |

# Study results