

# Detection of stress in newborns during intubation by means of skin conductance measurements.

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Determining the effectiveness of commonly used premedicating agents in reducing subclinical stress responses in newborns during intubation.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON34328

### Source

ToetsingOnline

### Brief title

SCM and intubation

### Condition

- Other condition
- Respiratory tract therapeutic procedures

### Synonym

pain, stress

### Health condition

stress cq pijn

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Isala Klinieken

**Source(s) of monetary or material Support:** geen financiering

## Intervention

**Keyword:** intubation, newborn, Skin conductance measurements

## Outcome measures

### Primary outcome

Skin conductance parameters: peaks / second

### Secondary outcome

Derived skin conductance measurements (average peak and rise time)

Heart rate, blood pressure and oxygen saturation

Intubating conditions

## Study description

### Background summary

Internationally there is widespread variation in premedication before intubation of newborns, term and preterm. In the Isala Clinics Zwolle, The Netherlands we use morphine and vecuronium.

There are reasons to look for an alternative for morphine and vecuronium. The pharmacokinetic profile of morphine is unfavourable making it relatively unsuitable for acute interventions. Neuromuscular blockade with vecuronium does improve intubating conditions. However, the effect lasts relatively long, resulting in unwanted higher ventilating pressures.

Propofol is a relatively new anesthetic compound with rapid onset and short duration of action. It provides deep hypnosis and possibly has some analgetic effect. Since the RCT by Ghanta et al. (2007) propofol is increasingly used in neonatology.

Intubation is known as a painful procedure. Until now we do not have information about analgesia during intubation, since neuromuscular blockade and deep sedation prevent clinical assessment of pain. Therefore we want to use skin conductance measurements to gain insight in subclinical stress responses during the intubation procedure.

Our hypothesis is that despite premedication the stress response is still present during the intubation procedure.

### **Study objective**

Determining the effectiveness of commonly used premedicating agents in reducing subclinical stress responses in newborns during intubation.

### **Study design**

Prospective randomized open observational intervention study.

### **Intervention**

not applicable

### **Study burden and risks**

No burdens or risks.

## **Contacts**

### **Public**

Isala Klinieken

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

All newborns requiring endotracheal intubation

### Exclusion criteria

Congenital Heart Disease

Hypotension

(Suspected) congenital metabolic disorder

(Suspected) chromosomal disorder

## Study design

### Design

**Study type:** Interventional

Masking: Single blinded (masking used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2010

Enrollment: 20

Type: Anticipated

### Medical products/devices used

Product type: Medicine

Brand name: Lipuro

Generic name:	Propofol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	morphine
Generic name:	morphine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Norcuron
Generic name:	vecuronium
Registration:	Yes - NL intended use

## Ethics review

Approved WMO	
Date:	12-10-2010
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	
Date:	04-11-2010
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

## 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

EudraCT

CCMO

### ID

EUCTR2010-021887-13-NL

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