# Is the mask or nasal tube better as interface during respiratory support of preterm infants at birth?

Gepubliceerd: 22-10-2009 Laatst bijgewerkt: 19-03-2025

The hypothesis is that using nasal tube as interface during stabilisation of preterm infants at birth is more effective compared to mask.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving tijdelijk gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27370

**Bron**
NTR

**Verkorte titel**
MOUNTAIN

**Aandoening**

neonatal resuscitation

### Ondersteuning

**Primaire sponsor:** Leiden University Meidcal Center
**Overige ondersteuning:** none

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The need for intubation in the first 24 hours after birth.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Randomised controlled trial of interface use during stabilisation of preterm infants in the delivery room.

Hypothesis:

Resuscitation of infants between 24 and 30 weeks gestation is more effective using a nasal tube than a face mask as an interface with the Neopuff Infant Resuscitator (Neopuff) as the manual ventilating device.

Aim:

To compare two resuscitation device interfaces; the nasal tube with a face mask using the Neopuff Infant Resuscitator to stabilise newly born infants between 24 and 30 weeks gestation in the delivery room (DR).

Research plan:

Infants between 24 and 30 completed weeks gestation born at Leiden University Medical Center and requiring positive pressure ventilation in the delivery room will be randomly allocated to either the nasal tube or face mask.

Primary objective:

To determine whether the response to ventilation in the DR using a nasal tube compared to a face mask reduces the risk of lung injury in newly born infants measured by the need for endotracheal intubation in the first 24 hours after birth.

### Doel van het onderzoek

The hypothesis is that using nasal tube as interface during stabilisation of preterm infants at birth is more effective compared to mask.

### Onderzoeksopzet

1. Birth;

2. 24 hours after birth.

**Onderzoeksproduct en/of interventie**

During respiratory support mask or nasal tube will be used as interface. National resuscitation guidelines will be followed.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Preterm infants, gestational age range 24-30 weeks (more than 24 weeks and not more than 29 weeks and 6 days).

## Belangrijkste redenen om niet deel te kunnen nemen

### (Exclusiecriteria)

Antenatal diagnosed congenital anomalies of the cardial or respiratory system or anomalies incompatible with survival.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving tijdelijk gestopt |
| (Verwachte) startdatum: | 17-05-2009 |
| Aantal proefpersonen: | 774 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 22-10-2009 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 32567
Bron: ToetsingOnline

Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL1944 |
| NTR-old | NTR2061 |
| CCMO | NL25699.058.08 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON32567 |

# Resultaten

**Samenvatting resultaten**
N/A