Gerandomiseerde studie naar het monitoren van longfunctie bij de opvang van te vroeg geborenen bij de geboorte

Gepubliceerd: 02-08-2013 Laatst bijgewerkt: 18-08-2022

To test the hypothesis that observing the data and waveforms displayed on an respiratory function monitor during the provision of positive pressure ventilation to preterm infants at birth will increase the proportion of tidal volumes within a...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23993

Bron
NTR

Verkorte titel
MONitoR

Aandoening

prematuriteit- prematurity
resuscitatie-resuscitation

Ondersteuning

Primaire sponsor: Leids Universitair Medisch Centrum, Leiden, The Netherlands
Overige ondersteuning: The Laerdal Foundation for Acute Medicine
Fisher & Paykel Healthcare Limited
Leiden University Fund (LUF/Den Dulk Moermans Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The proportion of tidal volumes delivered during manual PPV to an infant within the target range of safe tidal ventilation. The target range of adequate tidal volume is defined as 4-8 mL/kg.

Toelichting onderzoek

Achtergrond van het onderzoek

Extremely preterm infants often fail to establish efficient gas exchange independently in the delivery room (DR) and many receive mask ventilation or tracheal intubation and mechanical ventilation. However, immediately after birth the immature lung is highly vulnerable to injury.

Achieving effective manual ventilation can be difficult because most clinicians are not aware when mask leak or airway obstruction occur. With variable leaks, variable tidal volumes are delivered that may be either inadequate or excessive causing lung injury. Traditionally, adequacy of ventilation during positive pressure ventilation (PPV) in the DR is assessed by adequate chest rise and an increase in heart rate. Recently, it has been demonstrated that the use of a respiratory function monitor (RFM) can guide PPV in the DR, but data from large trial are lacking. The aim of this multicenter RCT is to test the hypothesis that observing the data and waveforms displayed on an RFM during the provision of PPV to preterm infants at birth will increase the proportion of tidal volumes within a predefined “safe range” of 4 – 8 mls/kg.

320 Infants between 24-27 weeks of gestation will be be randomised to either have the RFM visible or covered. Other than allocation of the visible or masked RFM, all other resuscitative measures (e.g. intubation, external cardiac massage, administration of oxygen and other drugs) will be at the discretion of the staff involved, following local protocols.

Primary outcome is the proportion of tidal volumes delivered during manual PPV to an infant within the target range of safe tidal ventilation. The target range of adequate tidal volume is defined as 4-8 mL/kg.
Participating centers:

1. Leiden University Medical Center, Leiden, the Netherlands

2. Department of Newborn Research, Royal Women’s Hospital, Melbourne, Australia

3. Maternal & Children’s University Hospital La Fe, Valencia, Spain

4. Intensive Care Pediatrics, V.Buzzi Children's Hospital, Milan, Italy

5. Karolinska University Hospital and Karolinska Institute, Stockholm, Sweden

Doel van het onderzoek

To test the hypothesis that observing the data and waveforms displayed on an respiratory function monitor during the provision of positive pressure ventilation to preterm infants at birth will increase the proportion of tidal volumes within a predefined “safe range” of 4 – 8 mls/kg.

Onderzoeksopzet

immediately after birth- discharge

Onderzoeksproduct en/of interventie

At birth positive pressure ventilation will be given with or without the guidance if a respiratory function monitor. The display of the monitor will be visible or covered.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Infants born will be included in this study if they are between 24 and 27 completed weeks gestation receiving PPV for resuscitation at birth and do not have a known abnormality which might interfere with breathing.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Infants will be excluded from the final analysis if they are found to have a congenital abnormality or condition that might have an adverse effect on breathing or ventilation, including: congenital diaphragmatic hernia, tracheo-oesophageal fistula or cyanotic heart disease.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-09-2013
Aantal proefpersonen:	320
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	02-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3939
NTR-old	NTR4104
Ander register	METC LUMC : P 12.295
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A