Tactile stimulation to improve spontaneous breathing in neonatal resuscitation

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

Summary

ID

NL-OMON43256

Source
ToetsingOnline

Brief title
Touch and go (TANGO)

Condition

- Respiratory disorders congenital
- Neonatal and perinatal conditions

Synonym
Prematurity, preterm birth

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Chiesi Farmaceutici,Chiesi Farmaceutici SpA

en Den Dulk Moerman LUF subsidie.

Intervention

Keyword: Breathing, Preterm, Resuscitation, Stimulation

Outcome measures

Primary outcome

The main study parameter is the average respiratory minute volume at 1-4

minutes after birth (from 60 seconds until 240 seconds after birth).

Secondary outcome

Secondary study parameters are;

o Average respiratory minute volume in the first 7 minutes after birth

o Average rate of rise to maximum tidal volumes in the first 7 minutes after

birth

o Percentage of time of given mask ventilation

o Oxygen saturation and heart rate in the first 10 minutes after birth

o Maximum oxygen needed in the first 10 minutes after birth

o Signs of exhaustion: a decrease in tidal volumes with lower peak inspiratory

flow waves and a shift in the frequency distribution (Siew 2015).

o Percentage of spontaneous breaths with tidal volumes above 4 ml/kg

o Percentage of spontaneous breaths with tidal volumes above 8 ml/kg

Study description

Background summary

Although ample research has improved our respiratory and hemodynamic care for very preterm infants during the neonatal period, our care at birth has been a

neglected area until recent years (te Pas 2008, van Vonderen 2014). For successful transition to life after birth some major respiratory and hemodynamic physiological changes have to occur (van Vonderen 2014, Hooper 2005). In preterm infants the immature respiratory system often complicates this transition at birth (Hooper 2005, Polglase 2012). Consequently, preterm infants often need respiratory support immediately after birth. To minimise injury, intubation and mechanical ventilation is now avoided and the focus of respiratory care has shifted to non-invasive ventilation (positive pressure support of breathing and/or ventilation via facemask)(van Vonderen 2012, O*Donnell 2012). In human infants, tactile manoeuvres (warming, drying and rubbing the back or the soles of the feet) to stimulate breathing have been recommended during the initial assessment of the infant at birth (Lee 2011). These interventions alone would help 10% of all infants that need assessment after birth to achieve spontaneous breathing (expert*s opinion) (Wall 2009). Because it is assumed that tactile stimulation during initial assessment promotes breathing, it is currently recommended in the international resuscitation guidelines (WHO 2012). Although this is commonly accepted intervention, there are no human studies demonstrating the effect of stimulation on breathing at birth, especially in preterm infants.

Study objective

The objective of this study is to compare the direct effect of repetitive tactile stimulation versus standard stimulation on the respiratory effort of preterm infants during stabilisation at birth.
The most ideal comparison would be to compare stimulation vs no stimulation, however most clinicians would not feel comfortable to abandon stimulation if they think the infant would need it. However, reviewing the delivery room recordings demonstrated that stimulation is frequently not performed.

Currently, multiple studies are conducted in our center to stimulate spontaneous breathing after birth. This study is one of the interventions that might be used for stimulating spontaneous breathing. The results of this study will be used for generating hypothesis/rationale for a larger randomized study with a primary clinical outcome in which all interventions will be included that have a positive outcome on stimulating spontaneous breathing.

Study design

The design of this study is a single blinded randomized clinical trial.

Intervention

For this study infants will be randomized to recurrent stimulation or standard stimulation after birth.

Recurrent tactile stimulation is hereby defined as gently rubbing of the back and the soles of the feet during 10 seconds. To prevent that the stimulatory effect (reflex) will extinct every 10 seconds of stimulation will be followed by 10 seconds without stimulation. The recurrent stimulation will take place in the first 4 minutes after birth (from 0 until 240 seconds after birth). Standard stimulation is conforming recommendation in the international guidelines. Gently rubbing the back and the soles of the feet will be performed when the clinicians consider the breathing to be insufficient or absent. After 4 minutes both groups are treated the same, stimulation can be given left to the discretion of the caregiver.

Study burden and risks

The study is group-related, most preterm infants breathe at birth, but this is often insufficient and respiratory support is needed. To minimise injury, intubation and mechanical ventilation is now avoided and the focus of respiratory care has shifted to non-invasive ventilation (positive pressure support of breathing (CPAP) and/or ventilation via facemask). The most gentle and effective way of providing respiratory care without causing injury is to stimulate and support spontaneous breathing. In addition the benefit of repetitive tactile stimulation is that it might increase respiratory effort, while the risks are negligible when the stimulation is gently applied.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm infants of 27-31+6 weeks of gestation can be randomized for receiving recurrent tactile stimulation or not.

Exclusion criteria

When an infant is included in the study, but the research protocol characterized for the allocated intervention is not strictly followed, the infant will be excluded for analysis and another infant will be included.
Infants will also be excluded 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, trachea-oesophageal fistula or cyanotic heart disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-09-2016
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	06-07-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	09-11-2016
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	NL57263.058.16