Touch ANd Go

No registrations found.

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

Summary

ID

NL-OMON27260

Source
NTR

Brief title
TANGO

Health condition

resuscitation
spontaneous breathing
preterm infant

Sponsors and support

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

Intervention

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

Rationale Repetitive tactile stimulation can increase the respiratory drive/effort in preterm infants at birth, potentially leading to less CPAP failure and less positive pressure ventilation would be needed that might be injurious.

Objective To compare the direct effect of repetitive tactile stimulation on the respiratory effort of preterm infants during stabilisation at birth.

Study design A single blinded randomized clinical trial.

Study population Preterm infants of 27-31 weeks of gestation.

Intervention Infants will be randomized to receive repetitive stimulation during stabilisation after birth or standard stimulation. Repetitive tactile stimulation is hereby defined as gentle rubbing of the back and the soles of the feet for every 10 seconds as soon as the infant is placed on the resuscitation table. To prevent that the stimulatory effect will extinct, every 10 seconds of stimulation will be followed by 10 seconds without stimulation. Standard stimulation is defined according to the international guidelines, where stimulation is

recommended initially if breathing is insufficient or absent.

Main study parameters/endpoints The main study parameter is the average respiratory minute volume at 1-4 minutes after birth (from 60 seconds until 240 seconds after birth).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness The research is group-related, because most preterm infants need respiratory support at birth. The most logical way to avoid potentially harmful ventilation is to stimulate and support spontaneous breathing at birth. Tactile stimulation has been recommended during the initial assessment but infants could benefit from repetitive stimulation of the respiratory effort. Repetitive tactile stimulation is non-invasive and when applied gentle risks are negligible.

Study objective

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). Although this is commonly accepted intervention, there are no human studies demonstrating the effect of stimulation on breathing at birth, especially in preterm infants. Because it is assumed that tactile stimulation during initial assessment promotes breathing, it is currently recommended in the international resuscitation guidelines (WHO 2012).

Currently, preterm infants are not dried, but placed in a plastic wrap to prevent hypothermia which may result in less stimulation (Rohana 2011, Morley 2007). Hereby, retrospective analysis of video recordings of stabilisation of preterm infants showed that tactile stimulation is often not performed. It is possible that applying stimulation repetitively augments the respiratory effort at birth and decreases the chance of CPAP-failure and the need for positive pressure ventilation.

Study design

The first 10 minutes after birth.

Intervention

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.

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Eligibility criteria

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:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2016
Enrollment:	44
Type:	Actual

Ethics review

Positive opinion

Date:	04-08-2016
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	NL5755
NTR-old	NTR6021
Other	METC : P16.072

Study results