Caffeine for breathing at birth

No registrations found.

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

Summary

ID

NL-OMON24252

Source
NTR

Brief title
CABAB

Health condition

neoantal transition, respiratory distress, neonate, caffeïne, breathing, tidal volume

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Chiesi Pharmaceutticals, Leids Univesitair Fonds

Intervention

Outcome measures

Primary outcome

Average respiratory minute volume at 7-10 minutes after birth

Secondary outcome

-Average Rate of rise to maximum tidal volume at 7-10 minutes after birth

-Time of mask ventilation given

-Oxygen saturation and heart rate in the first 10 minutes from birth

-Maximal oxygen needed in the first 10 minutes

-Total amount of pure oxygen given to the patient (oxygen load) will be calculated taking into consideration birth weight, tidal volume, respiratory rate, fraction of inspired oxygen (FiO2) and timing of stabilisation

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. For successful transition to life after birth some major respiratory and hemodynamic physiological changes have to occur. The transition is often hampered in very preterm infants because of the immature respiratory system. Consequently, preterm infants often need respiratory support immediately after birth.

In the recent years it has become evident that positive pressure ventilation can adversely affect the cardio-respiratory system and cerebral perfusion during this vulnerable period. Ventilation at birth can cause lung injury, initiating pulmonary inflammatory responses, resulting in systemic involvement. Furthermore, the inflammatory cascade and cerebral flow instability at birth can be a direct source for brain injury. This makes the degree of brain injury dependent upon the nature of the initial ventilation strategy employed.

There is now a progressive shift in the management of these infants towards avoiding intubation and mechanical ventilation by the use of non-invasive continuous positive airway pressure (CPAP) in babies capable of breathing spontaneously. However, most very preterm infants breathe at birth, but respiratory effort is weak and still a large proportion of these infants fail CPAP and need to be intubated and ventilated. Thus, to reduce the injury at birth, ventilation should be avoided if possible.

As standard of care, all preterm infants receive caffeine to stimulate their breathing and is the primary treatment for prematurity related apnoea’s. A large RCT has shown that caffeine is safe to use in preterm infants, reduces the incidence of bronchopulmonary dysplasia and

improves long term outcome.

Caffeine is standard treatment in infants born <30 weeks of gestation, with the first dose administered either in the delivery room or in the NICU. Some NICU centres recommend to start caffeine right after birth as, it is possible that there is a direct effect and stimulate breathing at birth. In this way the stimulated breathing effort has the potential to increase the chance for a smoother transition at birth.

When caffeine has a direct effect at birth and improves respiratory effort, then this treatment could have the potential to decrease the chance that preterm infants show respiratory failure during transition. The benefit of this is that ventilation during the most vulnerable period, directly after birth, could then be avoided and less lung injury would occur.

Although there are a few studies reporting the effect of caffeine on respiratory effort, so far no data has been published reporting the direct effect and also there are no studies describing the effect on respiratory effort at birth. We wish to perform a pilot study to investigate the effect of caffeine on the respiratory effort of preterm infants at birth. The results of this study will be used for generating hypothesis/rationale for a larger randomized study with a primary clinical outcome.

Study objective

When caffeine has a direct effect at birth and improves respiratory effort, then this treatment could have the potential to decrease the chance that preterm infants show respiratory failure during transition. The benefit of this is that ventilation during the most vulnerable period, directly after birth, could then be avoided and less lung injury would occur.

Study design

Directly after after birth respiratory function measurements are conducted during stabilisation (approximately the first 10 minutes of life).

Intervention

As soon as possible after birth caffeine 10 mg/kg will be given intravenously. Birth weight will be calculated using estimated fetal weight or the expected weight based on the gestational age.

Caffeine administration at birth: The umbilical cord is disinfected with chlorhexidine. A green butterfly needle (21G) prefilled and attached to a 5 mL syringe with NaCl 0.9%. will be placed in the umbilical vein, endovascular location will be confirmed. Then caffeine is given (10 mg/kg), after which another flush with NaCl 0.9 % is given.

Caffeine after arrival in the unit: As soon the nurse has placed an intravenous catheter caffeine 10 mg/kg will be given intravenously.

In both groups daily caffeine administration will be continued conform local guidelines.

Contacts

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Eligibility criteria

Inclusion criteria

Infants born in LUMC with a gestational age < 30 weeks of gestation

Exclusion criteria

Infants will 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):	05-11-2014
Enrollment:	30
Type:	Actual

Ethics review

Positive opinion

Date:	05-11-2014
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	NL4691
NTR-old	NTR4896
Other	METC LUMC : P14.202

Study results