Caffeine treatment for stimulation of spontaneous breathing in preterm infants at birth

Published: 23-10-2014
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To investigate the direct effect of caffeine on the respiratory effort of the preterm infant at birth.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41183

Source
ToetsingOnline

Brief title
CAffeine for Breathing At Birth

Condition

- Neonatal respiratory disorders

Synonym
improvement of breathing of neonates, Respiratory function due to caffeine treatment

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Veni beurs dr. A.B. te Pas

Intervention

Keyword: Breathing, Caffeine, Neonate, Tidal volume

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 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

To investigate the direct effect of caffeine on the respiratory effort of the preterm infant at birth.

Study design

Randomized study

Study burden and risks

All measurements are observational and will not influence the treatment of the neoanate. Giving Caffeïne directly after birth or on the unit is according to protocol. Only the timing of administering Caffeïne will be randomized. Therefore the burden and risks are mnimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm infants born <30 weeks GA.

Exclusion criteria

Congenital abnormalities or condition that might have an adverse effect on breathing or

ventilation, including: congenital diaphragmatic hernia, trachea-esophageal fistula or cyanotic heart disease.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2014
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO Date:	23-10-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Not approved Date:	04-12-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	23-03-2016
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	NL50165.058.14