

Caffeine for breathing at birth

Gepubliceerd: 05-11-2014 Laatste bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24252

Bron

NTR

Verkorte titel

CABAB

Aandoening

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

Ondersteuning

Primaire sponsor: Leiden University Medical Center

Overige ondersteuning: Chiesi Pharmaceuticals, Leids Univesitair Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Average respiratory minute volume at 7-10 minutes after birth

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

LUMC
Janneke Dekker
Albinusdreef 2
Leiden 2333 ZA
The Netherlands
071-5266641

Wetenschappelijk

LUMC
Janneke Dekker
Albinusdreef 2
Leiden 2333 ZA
The Netherlands
071-5266641

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	05-11-2014
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	05-11-2014
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	NL4691
NTR-old	NTR4896
Ander register	METC LUMC : P14.202

Resultaten