Reducing Apneas in Preterm Infants: Low-Flow versus Caffeine

Published: 20-05-2014
Last updated: 20-04-2024

The main objective of this study is to determine if Low-Flow is non inferior in reducing apneic spells compared to caffeine. Secondary objectives are investigating if these treatments have an effect on the need of supplemental ventilation and on the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neonatal respiratory disorders
Study type	Interventional

Summary

ID

NL-OMON40827

Source
ToetsingOnline

Brief title
RALFC

Condition

- Neonatal respiratory disorders

Synonym
Shallow breathing because of prematurity

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Enschede

Intervention

Keyword: Apnea, Caffeine, Low-Flow, Prematurity

Outcome measures

Primary outcome

The primary outcome is treatment failure. Treatment failure is defined as less than 50% reduction in apneic spells (as measured over a period identical to the baseline measurement period).

Secondary outcome

A secondary objective of this study is to determine the combined effect of Low-Flow and caffeine in reducing apneic spells. Other secondary objectives of this study are to determine the effect of the therapies on the need of supplemental ventilation and the duration of hospitalisation.

Other study parameters of this study are the use of ventilation before inclusion and the use of maternal and co-medication during this study.

Study description

Background summary

Apnea of prematurity (AOP) is a common clinical development disorder of respiratory control in preterm infants. Because of this prematurity these infants sometimes experience a transient cessation of respiration, also called apnea or apneic spell. Two interventions used in reducing apneic spells in preterm infants with apnea of prematurity are caffeine and Low-Flow. Both treatments are common practice and used frequently, separately and sometimes even simultaneously. There is, however, no evidence which of these treatments to start first and the choice often varies between the physicians and their clinical expertise. To our knowledge caffeine therapy has never been compared

to Low-Flow therapy through nasal cannula in preterm infants with AOP.

Study objective

The main objective of this study is to determine if Low-Flow is non inferior in reducing apneic spells compared to caffeine. Secondary objectives are investigating if these treatments have an effect on the need of supplemental ventilation and on the duration of hospitalisation.

Study design

This will be a multicenter, randomized controlled trial.

Intervention

The interventions in this study are Low-Flow and Caffeine.

Fase I:
Group I will receive Low-Flow with heated and humidified room air (21% oxygen), which will be administered via nasal cannulae at a flow rate of 1.0 l/min.
Group II will receive a loading dose of caffeine base (10 mg/kg), given orally; then a daily maintenance dose (5 mg/kg) is given orally as per standard practice.

Fase II:
If treatment has failed in fase I the infant will move on to fase II and receive both therapies.

Study burden and risks

The risks of participation are considered minimal. The procedures participants undergo in this study are not different from regular treatment. The procedures are anthropometric measurements (height, weight, head circumference), physical examination (which includes auscultation) and treatment with either Low-Flow and/or caffeine; all common practices in the neonatal care. For this reason we believe that the interventions are neither stressfull nor harmfull to this group of infants. This study is of great therapeutic relevance, because of the lack of evidence of treatment of first choice for AOP.

Contacts

Public
Medisch Spectrum Twente

Haaksbergerstraat 55
Enschede 7513 ER
NL
Scientific
Medisch Spectrum Twente

Haaksbergerstraat 55
Enschede 7513 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Preterm infants admitted to the department of neonatology are eligible for the study if:
- born between 32 and 36 weeks of gestational age,
- are considered clinically stable, receive no CPAP,
- they experience 4 or more apneic spells in 3 hours; 4 apneic spells in 12 hours or less or 8 apneic spells in 24 hours or less.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- If other forms of ventilation or continues positive airway pressure are required;
- If apneic spells are due to other causes of apnea than AOP, such as infection, metabolic disturbances, respiratory compromise, cardiovascular disturbances, central nervous system abnormalities, hematologic imbalance, gastrointestinal abnormalities, disturbance in thermoregulation, or side effects of medication;

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2014
Enrollment:	290
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Caffeine
Generic name:	Caffeine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	20-05-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	28-05-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
EudraCT	EUCTR2013-005568-24-NL
CCMO	NL47657.044.14