Stabilisation of preterm infants with intact umbilical cord: feasibility study

Published: 21-09-2016
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To test the safety of using the Con-Cord table for stabilization of preterm infants according to the ABC approach.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON45857

Source
ToetsingOnline

Brief title
Aeration, Breathing, Clamping project, study 1 (ABC 1 study)

Condition

- Neonatal and perinatal conditions

Synonym
delayed cord clamping, resuscitation table

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: aeration, cord clamping, premature, stabilisation

Outcome measures

Primary outcome

safety and feasibility measures. Primary outcome will be the success in

supporting preterm infants according to local guidelines while the umbilical

cord is intact and not stretched)

Secondary outcome

NA

Study description

Background summary

Most preterm infants fail to aerate their immature lungs at birth and need respiratory support for stabilisation. Cord clamping before lung aeration then compromises cardiovascular function. Delaying cord clamping until the lung has aerated is beneficial for preterm infants for a more stable hemodynamic transition and also placental transfusion, for which breathing is an important driving force. Until this was impractical to do, but a resuscitation table (the Con-Cord table) has been designed to make it possible in preterm infants to keep the cord intact until the lung has aerated and the infant is respiratory stable and breathing (the Aeration Breathing Clamping (ABC) approach).

Before a large RCT can be planned with important clinical outcome we need to test the safety and effectiveness of the new medical device (Con-Cord table) and the ABC approach. Three consecutive studies will be performed: 1) feasibility study, 2) effectiveness study and 3) clinical randomized trial.
This is part one of the project: the feasibility study.

Study objective

To test the safety of using the Con-Cord table for stabilization of preterm infants according to the ABC approach.

Study design

a feasibility study

Intervention

Preterm infants will be stabilized on the according to the ABC approach

Study burden and risks

Using the Con-Cord table that is designed to perform the ABC approach while all care can be provided that is similar to a standard resuscitation table and we expect no additional burden or risk next to prematurity related risk. There is also no extra risk to keeping the cord intact until the infant is stabilized.
There are potential benefits, but a larger RCT is needed to confirm this.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants of 26-34 weeks gestational age and no other complications than preterm birth are expected and there are no signs of severe fetal distress. Both, infants born vaginally as well as infants born after caesarean section may be included. A minimum of 5 infants born by caeserean section will be included.

Exclusion criteria

Signs of placental abruption or placenta praevia.
Emergency caesarean section, ordered to be executed within 15 minutes.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2016
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	Con-Cord table
Registration:	No

Ethics review

Approved WMO

Date:	21-09-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	15-11-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-03-2017
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	06-10-2017
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	NL57810.058.16