Stabiliziation of preterm infant with intact umbilical cord: a feasibility study

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	-

Summary

ID

NL-OMON21731

Source
NTR

Brief title
ABC study 1

Health condition

prematurity, resuscitation, cord clamping

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

After each infant the complete procedure, data and aspects of resuscitation will be evaluated. Any safety issues or problems with the SLT will first be resolved before the next infant will be included.

We will evaluate the following items:

The preterm infant

- the platform can be placed close to the introïtus

- the infant is placed on the table in the right position

- the cord is not kinked or stretched

- wrap is placed without a problem

- time needed to start support < 90 seconds

- oximetry probe can be placed by the nurse in a timely manner

- respiratory support can be given in an adequate manner

- no moderate to severe hypothermia at admission

The neonatologist

- can easily apply interventions to the infant

- can easily reach for the dials of the ventilation device and oxygen blender

- is able to read the monitor during the stabilization

The neonatal nurse

- is able to assist the neonatologist without obstruction

The obstetrician

- can assist birth of the preterm infant conform standard care

- can unobstructed monitor the mother (and fetus number 2)

- can monitor/assist in the third stage of labour conform standard care

The obstetric nurse

- is able to assist the neonatologist without obstruction

The mother

- can give birth to her baby in an unobstructive manner

- can freely touch (and stimulate) her baby

Secondary outcome

Baseline characteristics: Gestational age, birth weight, sex, single or twin deliveries, monochorionic (with or without fetoscopic laser treatment) of dichorionic, IUGR (< 10th percentile birth weight)

Study description

Background summary

Rationale:

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 now 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.

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.

Study population: infants of 26-35 weeks of gestation.
Intervention: Preterm infants will be stabilized on the Con-Cord table according to the ABC approach.

Main study parameters/endpoints: 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.

Study objective

It is safe and feasible to use the Con-Cord table for the ABC approach for stabilisation of preterm infants at birth.

Study design

first 10 minutes of life after birth

Intervention

Preterm infants will be stabilized according to the Aearation, Breathing, then Clamping (ABC) approach. As soon as the infant is born, the infant will be placed on the Con-Cord table and respiratory support will be given according to the local resuscitation guidelines. The umbilical cord will not be clamped until the infant is stabilized and breathing.

With the exception that the infant is stabilized close to the mother and the cord is clamped in a later stage, the infant will receive standard treatment.

Contacts

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Eligibility criteria

Inclusion criteria

Infants of 26-35 weeks gestational age born vaginally and no other complications than preterm birth are expected and there are no signs of fetal distress.

At this moment it is not possible to use the table in the OR, only vaginally born infants will be included

Exclusion criteria

Signs of placental abruption or placenta praevia

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	26-09-2016
Enrollment:	15
Type:	Unknown

Ethics review

Positive opinion

Date:	26-09-2016
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	NL5907
NTR-old	NTR6095
Other	: 25330

Study results