Starting respiratory support prior to cord clamping in preterm infants to improve pulmonary en circulatory transition immediately after birth: effectivenss study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19967

Source
Nationaal Trial Register

Brief title
ABC2

Health condition

Preterm infants, transition, resuscitation, cord clamping. Premature kinderen, transitie, resuscitatie, afklemmen navelstreng.

Sponsors and support

Primary sponsor: Leiden University Medical Centre
Erasmus MC - Sophia Children's Hospital.
Source(s) of monetary or material Support: NWO
Gisela Thier Fund
Sophia Children's Hospital Foundation

Intervention

Outcome measures

Primary outcome

The primary outcome will be the time needed to stabilise the infant, starting from birth and defined as the establishment of regular spontaneous breathing evaluated on the respiratory function monitor, a heart rate ≥ 100 bpm and oxygen saturation above 90% while using FiO2 < 0.40.

Secondary outcome

The time point after birth when respiratory support was started and oximeter signals could be interpreted.

The occurrence the ABC approach could not be performed and reason why.

Failure of reaching the primary outcome within 10 minutes from birth.

Duration of mask ventilation given.

Average pressures given during mask ventilation.

Average pressure given during mask CPAP.

Oxygen saturation and heart rate in the first 10 minutes from birth.

Time point of cord clamping.

Problems occurring with the cord before cord clamping.

Occurrence of the need for cord clamping before stabilisation.

The occurrence of the necessity for intubation in the DR.

The occurrence of hypothermia at admission in the NICU.

Apgar scores.

Echocardiography measurement: ductal flow ratio at 1 hour of age.

Maternal blood loss.

The occurrence of postpartum haemorrhage.

The occurrence of surgical site wound infection after caesarean section.

Study description

Background summary

Experimental studies have shown that assuring lung aeration and ventilation before cord clamping results in more stable cardiovascular transition at birth. Our newly designed resuscitation table, the Concord, allows to delay cord clamping in preterm infants until the infant is stabilised; an approach considered as Physiological-Based Cord Clamping (PBCC). Feasibility of PBCC with the Concord has been tested and confirmed. In this study our objective is to test whether stabilisation of preterm infants (24 - 31 weeks) performing PBCC using the Concord is at least as effective when compared to the standard approach using the standard resuscitation table. We wil perform a multicenter randomized controlled non-inferiority trial and the primary outcome will be the time needed to stabilize the infant, starting from birth.

Study objective

Stabilisation of preterm infants performing physioloigcal based cord clamping using the Concord is at least as effective as stabilisation according to the standard approach using the standard resusciation table.

Study design

The intervention is immediately after at birth and restricted to PBCC or regular support of transition. All other clinical care is according to standard local protocols with no difference between the intervention and control group.

Intervention

Preterm infants randomized to the intervention group will be stabilized according to physioloigcal based coord clamping (PBCC). As soon as the infant is born, the infant will be placed on the Concord (a purpose-built resusciation table) and respiratory support will be started according to the local resuscitation guidelines. The umbilical cord will not be clamped until the infant is stabilised, defined as the establishment of regular spontaneous breathing evaluated on the respiratory function monitor, a heart rate ¡Ý 100 bpm and oxygen saturation above 90% while using FiO2 < 0.40.

Preterm infants randomized to the control group will receive delayed cord clamping (DCC) for 30-60 seconds and will be subsequently stabilised according to standard local resusciation guidelines on a regular resuscitation table.

Contacts

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Eligibility criteria

Inclusion criteria

Infants born between 24 and 31 weeks of gestational age and no other complications than preterm birth are expected.

Exclusion criteria

Significant congenital malformations influencing cardiopulmonary transition.

Signs of placental abruption or placenta praevia.

Signs of severe fetal distress.

Emergency caesarean section (ordered to be executed within 15 minutes).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	24-04-2018
Enrollment:	64
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-04-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46753
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7004

Register	ID
NTR-old	NTR7194
CCMO	NL64454.058.18
OMON	NL-OMON46753

Study results