Delayed Umbilical Cord Clamping Amphia Study - ALAAF study

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

Summary

ID

NL-OMON55441

Source
ToetsingOnline

Brief title
Delayed Umbilical Cord Clamping Amphia Study

Condition

- Neonatal and perinatal conditions

Synonym
Delayed umbilical cord clamping

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Amphia Academie en zo nodig vakgroep Gynaecologie en Kindergeneeskunde

Intervention

Keyword: caesarean, cord clamping, neonate, transfusion

Outcome measures

Primary outcome

Outcomes will be divided in primary and secondary outcomes. Main infant study outcomes will be 1) Haemoglobin and haematocrit concentrations 48 hours after birth, 2) APGAR score and 3) Rectal temperature.

Secondary outcome

Secondary outcomes will be divided into maternal outcomes and outcome of infants.

Maternal outcomes:

1. Maternal blood loss during caesarean section.

2. Need for maternal blood transfusion.

3. Maternal infections in the postnatal period (6 weeks period)

Infant outcomes:

1. Complete serum bilirubin value 2 days after birth

2. Ferritin and Hemoglobin values at the age of 4 months

Study description

Background summary

Multiple previous studies show a significant association between delayed umbilical cord clamping and improved post-partum transition for the infants.

Especially previous studies showed increased early haemoglobin concentrations and iron stores in infants. Despite the widespread implication of delayed umbilical cord clamping (DUCC) in the Dutch midwife practice and Dutch hospitals, previous studies only show small percentage of use of DUCC in caesarean sections. The available research regarding delayed umbilical cord clamping during caesarean section is limited. However, these studies assessed the parameters with a small group of patients. Therefore, the evidence for DUCC in caesarean sections is scarce. We aimed to study the neonatal and maternal effects with DUCC in caesarean sections compared to early umbilical cord clamping (cord milking).

Study objective

This study will evaluate if neonatal effects as described in previous studies are seen in delayed umbilical cord clamping in caesarean sections. Moreover, we will review the maternal effects compared to conventional cord milking in caesarean sections.

Study design

This study will be organised as a randomised prospective cohort study in a secondary referral clinical (Amphia Hospital Molengracht, Breda).

Intervention

There will be a randomisation in two groups for the complete study population of approximately 100 study objects. Randomisation will be 1) Cord milking and 2) Delayed umbilical cord milking.

Study burden and risks

This study required additional blood examination of infants in the first days of life. In total, two additional blood examinations will complete this study. Further additional research is not necessary. No burden or adverse events will be associated with participation. If the maternal of infants condition is inadequate to participate in this study, standard practice will be used (cord milking). Because of potential risks in a vulnerable study population this study will be supervised by a DSMB. This board will monitor the risks and benefits of this study and if necessary will adjust the protocol of the study. A neonatologist, gynaecologist and epidemiologist will participate in this board. Meetings and agreements are available in this study protocol and in the DSMB-charter.

Contacts

Public
Amphia Ziekenhuis

Molengracht 21
Breda 4818CK
NL
Scientific
Amphia Ziekenhuis

Molengracht 21
Breda 4818CK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Primary cesarean section
- Duration of pregnance between 37 and 42 weeks

Exclusion criteria

- Secundary cesarean section
- Maternal clotting disorder
- Maternal irregular antibodies
- Maternal fever
- Prelabor rupture of the membranes (PROM) > 24 hours
- Caesarean section indicated because of placenta praevia

- Caesarean section performed under general anesthesia

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-10-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	12-04-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-01-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20503
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65977.100.18

Study results

Date completed:	18-08-2022
Results posted:	06-09-2024
Actual enrolment:	115

First publication
01-03-2024