ALAAF-STUDIE

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Delayed umbilical cord clamping (DCC) can improve neonatal transition in term of heart rate and respiratory condition and stimulate placental transfusion with higher concentrations of hemoglobin and hematocrit post-partum. The possible maternal side...

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20503

Source
Nationaal Trial Register

Brief title
ALAAF

Health condition

Caesarean section

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Neonatal: Hemoglobin concentration (Ht), Hematocrit concentration (Ht)

Secondary outcome

Neonatal: APGAR score, rectal temperature, total serum bilirubin concentration at day 4, total ferritin concentration at age of 4 months Maternal: Total amount of blood loss, need for blood transfusion, maternal infection post-partum

Study description

Background summary

Introduction: Multiple previous studies showed a significant association between delayed umbilical cord clamping (DCC) and improved post-partum transition for the infant. Especially previous studies showed increased early hemoglobin and hematocrit concentrations and iron stores in infants. Despite the widespread implication of DCC in the Dutch midwife practice and Dutch hospitals in vaginal delivery, previous studies only show small percentage of use of DCC in caesarean sections. The available research regarding DCC during caesarean section is limited. However, these studies assessed the parameters with a small group of patients. Therefore, the evidence for DCC in caesarean sections is scarce. We aimed to study the neonatal and maternal effects with DCC in caesarean sections compared to cord milking. Objective: This study will evaluate if neonatal effects as described in previous studies are seen in DCC 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 cohort study in a secondary referral clinic (Amphia Hospital Langendijk, Breda). Study population: Infants born at term by caesarean section. Congenital screening was without deformities or indication for syndromes. 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 (DCC). Main study parameters/endpoint: Outcomes will be divided in primary and secondary outcomes. There will also be evaluated between infant outcomes and maternal outcomes. Main infant study outcomes will be 1) Haemoglobin and haematocrit concentrations Nature and extent of the burden and risks associated with participation, benefit and group relatedness: This study required additional blood examination of infants in the first days of life. In total, three 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 data safety monitoring board (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.

Study objective

Delayed umbilical cord clamping (DCC) can improve neonatal transition in term of heart rate and respiratory condition and stimulate placental transfusion with higher concentrations of hemoglobin and hematocrit post-partum. The possible maternal side-effects, such as blood

loss or need for transfusion, will be limited.

Study design

1 hour, 4 days, 6 weeks and 4 months after intervention

Contacts

Public
Amphia Hospital Breda
Eldin Krijgh

010-7040704
Scientific
Amphia Hospital Breda
Eldin Krijgh

010-7040704

Eligibility criteria

Inclusion criteria

Maternal criteria: Primary caesarean section, infants born between 37 and 42 weeks of gestational age (GA) Prenatal criteria: Prenatal screening without congenital abnormalities or syndromes

Exclusion criteria

Secundary caesarean section for maternal or neonatal indication, gemelli pregnancy, maternal coagulation disorder, maternal irregular antibodies, maternal fever (> 38 degrees Celsius) prior to the caeserean section, prelabor rupture of the membranes (PROM) (> 24 hours), placenta praevia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2019
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55441
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7629
CCMO	NL65977.100.18
OMON	NL-OMON55441

Study results