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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20503

Bron
Nationaal Trial Register

Verkorte titel
ALAAF

Aandoening

Caesarean section

Ondersteuning

Primaire sponsor: Not applicable
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

Publiek

Amphia Hospital Breda
Eldin Krijgh

010-7040704

Wetenschappelijk

Amphia Hospital Breda
Eldin Krijgh

010-7040704

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2019
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55441
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten