Maternal and fetal/neonatal pharmacokinetics and - dynamics of corticosteroids during pregnancy as treatment for fetal lung maturation

Gepubliceerd: 14-01-2021 Laatst bijgewerkt: 18-08-2022

Individual blood concentrations with the same dosing regime

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25709

Bron
NTR

Verkorte titel
MaDyCo study

Aandoening

(Imminent) preterm birth

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To examine the pharmacokinetics in maternal blood of standard regimen

Toelichting onderzoek

Achtergrond van het onderzoek

Preterm birth (PTB), occurring in 1015% of all pregnancies, is the leading cause of perinatal mortality and morbidity with longterm adverse consequences for postnatal health. The outcome after preterm birth was largely improved by the clinical introduction in the 70’s of antenatal corticosteroids (ACS), which are still administrated in a “one dose fits all”principle. However, it is known for over a decade that several factors influence the available maternal concentrations of ACS, while the safety of the universal dosage regime was recently questioned as prenatal exposure to ACS resulted in a higher incidence of mental and behavioral disorders in childhood. We propose to investigate, reevaluate and optimize the current ACS dosage regime to generate a personalized drug therapy approach to improve preterm neonatal outcome.

Doel van het onderzoek

Individual blood concentrations with the same dosing regime

Onderzoeksopzet

After administration of corticosteroids (t=0), blood samples will be drawn at t0, t0-30 min, t 1-3 hr, t 5-8 hr, t 10-12 hr and t20-24 hr. Measurement of corticosteroid concentration will be performed in maternal and umbilical cord blood by using the validated method of LC-MS/MS chromatography (corticosteroidassay (ISO 15189).

Onderzoeksproduct en/of interventie

Corticosteroids

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1) Older than 18 years of age.
2) Admitted at the Department of Obstetrics at Erasmus MC – Sophia for suspicion of preterm birth with a gestational age of 23+5 weeks until 33+6 weeks.
3) Understanding of Dutch in speaking and reading.
4) Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1) Women unable or unwilling to agree with the procedures.
2) Women unable or unwilling to give written informed consent.
3) Women with acute obstetric complications requiring immediate delivery at time of admission.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	14-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9318
Ander register	METC Erasmus MC : MEC-2019-0650

Resultaten