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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25709

Source
NTR

Brief title
MaDyCo study

Health condition

(Imminent) preterm birth

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

To examine the pharmacokinetics in maternal blood of standard regimen

Secondary outcome

To examine the relation between diverse maternal factors and the pharmacokinetics of the primary objective.

Study description

Background summary

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.

Study objective

Individual blood concentrations with the same dosing regime

Study design

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).

Intervention

Corticosteroids

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	14-01-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results