Macrophages, monocytes and fetal growth restriction

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23444

Source
NTR

Brief title
N/A

Health condition

Fetal growth restriction

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Differences in macrophage and monocyte numbers and phenotype in maternal blood, placenta and cord blood

Secondary outcome

Functional status of macrophages and monocytes in maternal blood, placenta and cord blood in terms of cytokine secretion and response to pro- and anti-inflammatory triggers

Study description

Background summary

Pregnancy is an immunological challenge in which the maternal immune system must facilitate maternal-fetal tolerance, placental development and functioning, and defense for mother and child against pathogens. This study will focus on maternal macrophages and monocytes specifically. During pregnancy, maternal macrophages that reside in the decidua are involved in placental development, fetal trophoblast invasion into the uterine stroma and remodeling of the maternal placental arteries, angiogenesis and tissue remodeling. Although knowledge of the exact macrophage characteristics and functional activity throughout uncomplicated pregnancies remains largely unknown, maternal macrophages are thought to increase after fertilization and are predominantly of the M1 subset during implantation, followed by a mixed M1/M2-like pattern in the first trimester. During the remainder of pregnancy, macrophages decrease in number and mostly express an M2-like phenotype, related to the preservation of maternal-fetal tolerance. Common pregnancy complications like preeclampsia, preterm birth and recurrent pregnancy loss have earlier been associated with an increased number of inflammatory macrophages. Hypothetically, aberrant macrophage behavior is associated with impaired placental development early in FGR pregnancies, or with inflammatory or hypoxic events later on.

The primary objective is to analyze differences in macrophage and monocyte numbers and phenotype in maternal blood, placenta and cord blood between uncomplicated pregnancies and pregnancies complicated by FGR.
The secondary objective is to analyze the functional status of macrophages and monocytes in terms of cytokine secretion and response to inflammatory triggers.

This in an observational study that investigates numbers, phenotype and cytokine levels of macrophages and monocytes derived from the placenta, cord blood and maternal blood using flowcytometry, RT-PCR and Luminex. Macrophages will be isolated from the placenta and cord blood will be obtained after delivery. Monocytes will be derived from maternal blood during a routine pregnancy check-up around 30 weeks GA and during delivery. In addition, monocytes and macrophages will be stimulated with pro- and anti-inflammatory triggers. Data will be compared between uncomplicated pregnancies and pregnancies complicated by fetal growth restriction.

Study objective

We hypothesize that higher levels of pro-inflammatory macrophages in pregnancy are related to early placental developmental defects (i.e. decreased trophoblast invasion and SA development) or inflammation and oxidative stress later in gestation, causing or worsening

PI, hypoxia and compromising fetal growth.

Study design

30 weeks gestational age and peripartum

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

- Informed consent
- 18-40 years old
- Pregnant
- Gestational age (GA): 36-42 weeks
- Fetal growth restriction and adequate fetal growth

Exclusion criteria

- Smoking
- BMI >30
- Immune related disorders
- Fever/illness within the last month
- Fertility treatment (ovulation induction, intra-uterine insemination (IUI), in vitro fertilization

(IVF), intracytoplasmic sperm injection (ICSI))
- Major congenital abnormalities

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2021
Enrollment:	48
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

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9350
Other	METC UMCG : METc 2021/063

Study results