Macrophages and monocytes in uncomplicated pregnancy and fetal growth restriction

Published: 05-07-2021
Last updated: 04-07-2024

The goal of this study is to obtain insight into possible differences in macrophage and monocyte populations in uncomplicated pregnancies and pregnancies complicated by FGR.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON51245

Source
ToetsingOnline

Brief title
Macrophages, monocytes and fetal growth restriction

Condition

- Immune disorders NEC
- Foetal complications

Synonym
fetal growth problems, Fetal growth retardation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: FGR, Macrophages, Placenta, Pregnancy

Outcome measures

Primary outcome

Number and phenotype of macrophages and monocytes in maternal blood, placenta

and cord blood

Secondary outcome

Functional status of macrophages and monocytes: 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 adequately defend mother and child against pathogens. Several immune cell subsets are involved, including natural killer cells, T cells and macrophages. Inadequate immunological adaptations compromise placental functioning and are associated with pregnancy complications.

In this study, we will focus on the role of maternal macrophages and monocytes in uncomplicated pregnancies and fetal growth restriction. Inadequate adaptations of maternal macrophages can be associated with placental developmental defect and impaired maternal-fetal tolerance. Macrophage subset imbalances have earlier been associated with common pregnancy complications like preeclampsia, preterm birth and recurrent spontaneous pregnancy loss. However, the role of macrophages in fetal growth restriction is not completely understood.

Fetal growth restriction is a common pregnancy complication that affects 5-10% of all pregnancies and that is associated with increased child mortality and morbidity. Fetal growth restriction is due to placental insufficiency that can be caused or exacerbated at multiple levels. Most often it results from placental maldevelopment or placental inflammation and oxidative stress. Hypothetically, placental macrophages are involved since these cells are known

to have a role in placentation. This study aims to obtain a better understanding of the role of macrophages and monocytes in healthy pregnancies and the possible link between altered macrophage functionalities and the pathogenesis of FGR.

Study objective

The goal of this study is to obtain insight into possible differences in macrophage and monocyte populations in uncomplicated pregnancies and pregnancies complicated by FGR.

Study design

This is an observational study in which 24 women with healthy pregnancies and 24 women with a pregnancy complicated by FGR will be included. Macrophages and monocytes will be derived from placental biopsies, maternal blood and cord blood and will be analyzed using flowcytometry and RT-PCR. Numbers and phenotypes and cytokine secretion will be studied and macrophages and monocytes will be stimulated with pro- and anti-inflammatory triggers to determine their functional status. Maternal blood will be taking during routine blood sampling around 30 weeks of pregnancy and at labor. Placental samples and cord blood will be taken after delivery.

Study burden and risks

Obtaining placental samples and cord blood takes places after labor and therefore does not carry any risk nor burden. Maternal blood will if possible be taken during blood sampling for routine pregnancy check-ups. If necessary, an additional venapunction will take place, , the additional risk is negligible. This study will not benefit participating women personally, however, can on the long term lead to a better understanding and possibly therapeutic options for immune related pregnancy complications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

- Smoking
- Immune related disorders
- Fever/illness within the last month
- Fertility treatment (ovulation induction, intra-uterine insemination, IVF-ICSI)
- Major congenital abnormalities

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-06-2023
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	05-07-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL76611.042.21
Other	NL9350 (NTR)