Placental ULtraSound Evaluation in assisted reproductive technology

Published: 18-12-2019
Last updated: 15-05-2024

Is there a difference in morphological and vascular placental development between ART and naturally conceived pregnancies?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON48373

Source
ToetsingOnline

Brief title
PULSE-ART

Condition

- Other condition
- Placental, amniotic and cavity disorders (excl haemorrhages)

Synonym
reduced fertility, Subfertility

Health condition

subfertiliteit

Research involving
Human

Sponsors and support

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

Intervention

Keyword: ART, Morphology, Placenta, Vascularisation

Outcome measures

Primary outcome

Primary endpoints are morphological placental characteristics such as placental calcifications, placental lakes and placental location, and vascular placental characteristics such as vascularisation index.

Secondary outcome

Secondary endpoints are placenta biomarkers such as β-hCG, PAPP-A, PlGF and sFlt-1, foetal development, cell-free fetal DNA fraction in maternal plasma in NIPT and neonatal outcomes.

Study description

Background summary

Pregnancies after assisted reproductive technology (ART) are more at risk for adverse perinatal outcomes, such as pre-eclampsia and (very) low birthweight compared to pregnancies after natural conception. The aetiology behind this problem is not known, but there is evidence that the placenta plays an important role in mediating the effects of ART on adverse pregnancy outcomes. We therefore hypothesize that placental characteristics are different in ART-pregnancies compared to naturally conceived pregnancies. The Pulse-IVF study will focus on placental development in the first 20 weeks of gestation and will compare ART-pregnancies and naturally conceived pregnancies.

Study objective

Is there a difference in morphological and vascular placental development

between ART and naturally conceived pregnancies?

Study design

This is a prospective cohort study, in which the placenta and foetus of pregnant women will be investigated by ultrasound and Doppler at 5 times during pregnancy: at 8, 10, 12, 16 and 20 weeks of gestation. At 8, 12 and 20 weeks of pregnancy, blood will be drawn for the determination of placenta biomarkers. Participants are asked for permission to collect the results of the non-invasive prenatal test (NIPT) including the cell-free fetal DNA fraction (if applicable). At the end of pregnancy a delivery report will be requested from the midwife or gynecologist to obtain information on pregnancy outcomes such as birthweight, gestational age at delivery, maternal and neonatal complications.

Study burden and risks

Subjects will visit the hospital 5 times during pregnancy for an ultrasound and blood withdrawal (only on 3 time points). This might be experienced as a burden, however all appointments will be scheduled in consultation with each subject and will be combined with regular appointments as much as possible. There are no risks for participating in this study.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Maternal age >= 18 years
- Singleton pregnancy
- Naturally conceived or conceived after IVF or ICSI with or without pre-implantation genetic testing (PGT)
- Good understanding of the Dutch language
- BMI <= 35 kg/m2

Exclusion criteria

- Pregnant via other ART-treatments such as ovulation induction (OI), intra-uterine insemination (IUI) or controlled ovarian hyperstimulation (COH) only.

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):	13-02-2020
Enrollment:	264
Type:	Actual

Ethics review

Approved WMO

Date:	18-12-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22332
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL71273.068.19
Other	NL7973
OMON	NL-OMON22332