Het MURIM onderzoek

No registrations found.

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

Summary

ID

NL-OMON24778

Source
Nationaal Trial Register

Brief title
MURIM

Health condition

Repeated implantation failure, repeated miscarriage

Sponsors and support

Primary sponsor: Maastricht University Medical Centre (azM)
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The main study parameters are steroid profile in endometrial tissue and serum, activity of steroid enzymes, percentage of natural killer (NK) cells with an activating phenotype, determination of the vaginal microbiome using the inter spacer bacterial profiling (ISpro) technique and volatile organic compounds.

Secondary outcome

N/A

Study description

Background summary

Women with recurrent unexplained miscarriage (RM) and repeated implantation failure (RIF) are proposed to be at opposite ends of the implantation spectrum, with too receptive endometrium (implantation of genetically aberrant or poor quality embryos) versus too selective endometrium (no implantation even with genetically normal or good quality embryos). In both cases, no explanation for unsuccessful implantation has been found yet. Therefore, doctors can provide no therapeutic options other than supportive care on the way to a subsequent pregnancy.

The goal of this study is to elucidate whether there is a difference in endometrial parameters (determining endometrial receptivity) between women with reproductive failure: RIF and RM. Secondly we will investigate how the endometrial parameters of the women with RIF and unexplained RM compare with those of healthy, parous women to construct a receptivity profile for these women.

Study objective

We hypothesize there is a difference in endometrial parameters (determining endometrial receptivity) between women with reproductive failure: RIF and RM and healthy, parous women

Study design

n/a

Contacts

Public
Maastricht University Medical Centre
Linda Stevens Brentjens

+31(0)43-3875368
Scientific
Maastricht University Medical Centre
Linda Stevens Brentjens

+31(0)43-3875368

Eligibility criteria

Inclusion criteria

Repeated implantation failure:
• Female aged 18-38 years old
o the absence of implantation after two consecutive cycles of IVF or ICSI, or frozen embryo transfer cycles,
o where the cumulative number of transferred embryo’s was no less than 4 cleavage stage embryo’s or no less than 2 for blastocysts
• Primary or secondary infertility
• Written informed consent

Recurrent miscarriages
• Female aged 18-38 years old
• Repeated, unexplained miscarriages (RM) defined as 2 or more unexplained miscarriages not caused by abnormal parental karyotype, maternal thrombophilia and/or uterine abnormalities
• Written informed consent

Control
• Female aged 18-38 years old
• Uneventful previous pregnancy (minimal 1 child) defined as no preterm delivery, pre-eclampsia or fetal growth restriction, and live birth or presumed fertility
• Written informed consent

Exclusion criteria

Repeated implantation failure
• Clinically relevant intra-uterine pathology
• BMI > 35 kg/m2
• Untreated endocrine abnormalities
• PGD treatment
• Severe endometriosis (3th -4th degree)

Recurrent miscarriages
• Current or recent (<3 months ago) pregnancy, breastfeeding or hormonal contraceptive
• Current symptomatic genital infection
• BMI > 35 kg/m2
• Severe endometriosis (3th -4th degree)

Control group
• Previous miscarriages or implantation failure
• Current or recent (<3 months ago) pregnancy, breastfeeding or current hormonal contraceptive use
• BMI > 35 kg/m2
• Severe endometriosis (3th -4th degree)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-02-2019
Enrollment:	249
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Positive opinion

Date:	28-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 56176
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7571
CCMO	NL66835.068.18
OMON	NL-OMON56176

Study results

Summary results
N/A