MURIM: MUltidisciplinary Research on Implantation failure and Miscarriage

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sexual function and fertility disorders
Study type	Observational invasive

Summary

ID

NL-OMON56176

Source
ToetsingOnline

Brief title
MURIM

Condition

- Sexual function and fertility disorders

Synonym
infertility, Subfertility

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: Embryo, Endometrium, Implantation, Reproductive Failure

Outcome measures

Primary outcome

The main study parameters are steroid profile in endometrial tissue and serum,

activity of steroid enzymes, phenotype and function of Natural Killer cells,

presence of HLA antibodies, determination of the vaginal microbiome and

volatile organic compounds.

Secondary outcome

Not applicable

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.

Study objective

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, fertile women with a fertility treatment indication for another cause (such as male infertility or PGD).

Study design

This is a single-centre, observational cohort study. We will draw blood once, take a single endometrial biopsy and vaginal swab, and collect menstrual blood once to determine the endometrial profile of these women.

Study burden and risks

Women with RÏF, RM or fertile controls are invited for 1 extra visit to the MUMC+ for an endometrial biopsy, one blood sample and a vaginal swab. They receive a mooncup for collection of menstrual blood at home. From existing literature it is clear that the rate of adverse events is very low. It is of great importance to gain more insight in the physiology of embryo implantation and the pathofysiological processes that occur when an embryo fails to implant (no implantation, or repeated miscarriages). We lack diagnostical tools to discover the cause of reproductive failure in this category of women, which is an enormous emotional burden for these patients. By means of this study, attempts are made for the first time to gain more insight in these processes of implantation in women with succesful implantation in the past, repeated implantation failure and repeated miscarriages. Besides, there might be a small benefit for all participants as taking an endometrial biopsy could induce a higher change of pregnancy in subsequent menstrual cycles.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Repeated implantation failure
- Female aged 18-38 years old
- Repeated implantation failure (RIF) defined as:
- failure of implantation of three high quality embryo*s or after placement of ten or more embryo*s in multiple transfers
- 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 defined as no preterm delivery, pre-eclampsia or fetal growth restriction and live birth OR presumed fertile defined as an indication for PESA/TESE, female sterilisation, or PGD indication for genetic analysis without subfertility treatment
- Written informed consent

Exclusion criteria

Repeated implantation failure
- Clinically relevant intra-uterine pathology
- BMI > 35 kg/m2
- Untreated endocrine abnormalities
- PGD treatment

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

Control group
- Recurrent miscarriages or repeated 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 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):	09-04-2019
Enrollment:	249
Type:	Actual

Ethics review

Approved WMO Date:	31-12-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-11-2019
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-08-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-09-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-07-2022
Application type:	Amendment
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: 24778
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66835.068.18
OMON	NL-OMON24778