Het MURIM onderzoek

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24778

Bron
Nationaal Trial Register

Verkorte titel
MURIM

Aandoening

Repeated implantation failure, repeated miscarriage

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre (azM)
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

n/a

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	28-02-2019
Aantal proefpersonen:	249
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	28-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56176
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A