The relationship between age at menopause loci and the response of controlled ovarian hyperstimulation in women undergoing IVF: a candidate gene study.

Published: 23-12-2020
Last updated: 15-05-2024

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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-OMON54409

Source
ToetsingOnline

Brief title
RiSPONS: Risk Score to Predict Outcome of ovariaN Stimulation

Condition

- Sexual function and fertility disorders

Synonym
Infertility, menopause

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Bedrijven,Ferring

Intervention

Keyword: IVF, Polygenic risk score

Outcome measures

Primary outcome

The primary outcome parameter is the responsiveness of the ovaries to exogenous

FSH stimulation during IVF treatment, i.e. number of retrieved oocytes.

Secondary outcome

Secondary study parameters are other outcomes of the IVF treatment, described

by the number of follicles after stimulation, quality of retrieved oocytes,

quality of embryo*s as well as pregnancy rate and live-birth rate.

Study description

Background summary

Over the last decade genome-wide association studies (GWAS) have identified hundreds of common genetic variants (Single Nucleotide Polymorphisms, SNPs) associated with age of natural menopause (ANM). The peri-menopausal stage is preceded by a decrease in fertility eventually leading to sterility in the 10 years before menopause. Poor response to controlled ovarian hyperstimulation (COH) during IVF treatment is a reasonable predictor of diminished ovarian reserve. Therefore, we hypothesize that presence of genetic variants associated with earlier age of natural menopause might also be involved in diminished responsiveness of the ovaries to exogenous FSH stimulation during IVF treatment. In other words, patients that carry more SNPs associated with early age of menopause might as well have a poor response to COH treatment. Consequently, if that is the case, these SNPs might be used as a predictor for ovarian response during IVF treatment using polygenic risk scores.

Study objective

In this project, we hypothesize that presence of genetic variants associated with earlier age of natural menopause might be involved in diminished responsiveness of the ovaries to exogenous FSH stimulation during IVF treatment. Furthermore, we aim to investigate whether polygenic risk scores of genetic variants associated with age at natural menopause based on the large-scale GWAS are predictive of the response to IVF stimulation in patients starting their first IVF treatment cycle leading to a more patient-tailored care-setting.

Study design

This candidate gene study will be conducted in a retrospective as well as prospective cohort study.

Study burden and risks

Single blood sampling is needed to execute this candidate gene study, although this will be combined with standard blood sampling women will need to visit the hospital one extra time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- A regular menstrual cycle
- Undergoing IVF because of male infertility or unexplained infertility
- First cycle IVF treatment
- Age between 18 and 45 years

Exclusion criteria

- A history of ovarian surgery, chemotherapy of radiation therapy
- Non Northern European ethnicity

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-03-2021
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	23-12-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-06-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 28369
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL75062.078.20
OMON	NL-OMON28369