Measurement of AGD/2D:4D ratio

No registrations found.

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

Summary

ID

NL-OMON23108

Source
Nationaal Trial Register

Brief title
MEASURE

Health condition

PCOS, endometriosis and MRK syndrome

Sponsors and support

Primary sponsor: Amsterdam UMC - location VUmc
Source(s) of monetary or material Support: Amsterdam UMC - location VUmc

Intervention

Outcome measures

Primary outcome

The primary outcome is the difference in AGDac in all 4 groups.

Secondary outcome

Other study outcomes are:

- the difference in AGDaf and 2D:4D ratio in the four different patient groups (MRKH vs. PCOS

vs. endometriosis vs. controls).

The following parameters will also be monitored: age, ethnicity, BMI, medical history, signs of clinical hyperandrogenism (by questionnaire) and ovarian morphology by ultrasound (to investigate the presence of polycystic ovarian morphology).

Study description

Background summary

Mayer Rokitansky Küster Hauser (MRKH) syndrome is a congenital disorder, characterized by aplasia of the uterus and the upper two thirds of the vagina. The aetiology is unknown. We hypothesize that prenatal exposure to AMH is responsible for the development of MRKH in the female. The anogenital distance (AGD) and the ratio between the length of the 2nd and 4th digit (2D:4D ratio) have been described as biomarkers of prenatal androgen exposure. In women with polycystic ovary syndrome (PCOS) longer AGD is reported, suggesting that the origin of PCOS is possibly due to prenatal exposure to androgens. In women with severe endometriosis a decreased AGD has been reported, possibly due to oestrogenic intrauterine influence.
We will perform measurements by digital calliper of the AGD and 2D:4D ratio in women with MRK, PCOS, endometriosis and a control group.

Study objective

We hypothesize that prenatal exposure to AMH is responsible for the development of MRKH in the female. The anogenital distance (AGD) and the ratio between the length of the 2nd and 4th digit (2D:4D ratio) have been described as biomarkers of prenatal androgen exposure. In women with polycystic ovary syndrome (PCOS) longer AGD is reported, suggesting that the origin of PCOS is possibly due to prenatal exposure to androgens. In women with severe endometriosis a decreased AGD has been reported, possibly due to oestrogenic intrauterine influence.

Study design

Only one study visit for completing questionnaire and measurements.

Intervention

- measurement of AGD by digital calliper (AGDac, anterior clitoral surface to the centre of the anus; AGDaf, from the posterior fourchette to the centre of the anus)

- measurement of 2D:4D ratio by digital calliper

- measurement of 2D:4D ratio by computer-assisted analysis

Contacts

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Eligibility criteria

Inclusion criteria

4 groups:

MRK syndrome:

- Diagnosed with MRK

- age >18 years

PCOS:

- Diagnosed with PCOS

- age >18 years

endometriosis:

- Diagnosed with endometriosis

- age >18 years

Control:

- Age ¡Ý 18 years

- Regular, ovulatory cycle

- ICSI treatment for male infertility

Exclusion criteria

MRK syndrome:

no exlusion criteria

PCOS group:

- vaginal delivery in the medical history

- diagnosed with endometriosis

Endometriosis group:

- vaginal delivery in the medical history

- diagnosed with PCOS

Control group:

- diagnosed with PCOS/endometriosis

- ICSI treatment after a total fertilization failure in IVF cycle

- vaginal delivery in the medical history

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2018
Enrollment:	172
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48729
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7276
NTR-old	NTR7492
CCMO	NL64437.029.18
OMON	NL-OMON48729

Study results