Is MRKH syndrome caused by Intrauterine Placental Transfusion between sex-discordant twins? - measurement of AGD / 2D:4D ratio-

Published: 13-09-2018
Last updated: 15-05-2024

The aim of this study is to assess the relationship between the AGD, the 2D:4D ratio and the presence of MRKH syndrome, endometriosis and PCOS.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive tract and breast disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON48729

Source
ToetsingOnline

Brief title
MIPT 2.0

Condition

- Reproductive tract and breast disorders congenital
- Congenital reproductive tract and breast disorders

Synonym
Mayer Rokitanski Kuster Hauser syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 2D4D ratio, anogenital distance, MRK syndrome

Outcome measures

Primary outcome

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

Secondary outcome

Secondary 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.

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 androgens 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 want to study the biomarkers AGD and 2D4Dratio in this 3 gynaecological disorders, to study possible intrauterine exposure to hormones. (PCOS/MRK

andrenic exposure: longer AGD en lower 2D4D ratio, endometriosis oestrogenic exposure: shorter AGD and higher 2D4D ratio)

Study objective

The aim of this study is to assess the relationship between the AGD, the 2D:4D ratio and the presence of MRKH syndrome, endometriosis and PCOS.

Study design

Observational case control study.

Study burden and risks

This is a non-therapeutic study. In the course of this study we ask the subjects for one visit to the outpatient clinic for measurements of AGD and 2D:4D ratio.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081 HZ
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081 HZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

MRKH group (43 patients)
- Diagnosed with MRKH syndrome
- Age * 18 years
- signed informed consent ;PCOS group:(43 patients)
- Diagnosed with PCOS
- Age * 18 years
- signed informed consent ;endometriosis group: (43 patients)
- Diagnosed with moderate-severe endometriosis
- Age * 18 years
- signed informed consent ;Control group: (43 patients)
- Age * 18 years
- Regular, ovulatory cycle
- ICSI treatment for male infertility
- signed informed consent

Exclusion criteria

MRKH women
- not willing to participate in the study
PCOS group:
- vaginal delivery in the medical history
- diagnosed with endometriosis
- not willing or able to sign the informed consent;Endometriosis group:
- vaginal delivery in the medical history
- diagnosed with PCOS
- not willing or able to sign the informed consent;Control group:
- diagnosed with PCOS/endometriosis
- ICSI treatment after a total fertilization failure in IVF cycle
- vaginal delivery in the medical history
- not willing or able to sign the informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2018
Enrollment:	172
Type:	Actual

Ethics review

Approved WMO Date:	13-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 23108
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64437.029.18
OMON	NL-OMON23108