Is MRKH syndrome caused by intrauterine blood exchange between sex-discordant twins?

No registrations found.

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

Summary

ID

NL-OMON28058

Source
NTR

Brief title
MIPT study

Health condition

MRKH syndrome

Sponsors and support

Primary sponsor: VU university medical centre
Source(s) of monetary or material Support: VU university medical centre

Intervention

Outcome measures

Primary outcome

The primary outcome is the difference in occurrence of microchimerism (with an extra male cell line) in MRKH patients vs. controls.

Secondary outcome

The secondary outcome is the presence of chimerism in non-hematopoietic tissue (buccal cells) in MRKH patients.

Study description

Background summary

The aim of this study is to determine whether male microchimerism is present in patients with MRKH syndrome. This would be a result of intrauterine cell trafficking - and possible AMH transfer- from male to female co-twin.
Study design: Observational case control study.
In the course of this study we ask the subjects for one visit to the outpatient clinic or a home visit for blood sampling, collecting of a buccal smear and a short questionnaire.

Study objective

Our hypothesis is that MRKH patients are exposed to high concentrations AMH in utero, coming from their male co-twin (possible vanished twin). This AMH-exchange is possible because of intrauterine blood exchange between two fetuses. This blood exchange results in male (micro)chimerism in blood. Our aim is to study the presence of this male microchimerism in adult patients with MRKH.

Study design

Only one visit is necessary for blood sampling, buccal smear sampling and filling in a questionnaire (about medical history, family history, intoxications, BMI, age)

Intervention

96 patients with MRKH will be included. The controlgroup exists of 96 healthy women, already sampled. No interventions. Blood samples will be analyzed for Y-chromosome-specific real-time quantitative polymerase chain reaction.

Contacts

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Eligibility criteria

Inclusion criteria

- Diagnosed with MRKH syndrome

- Age ≥ 18 years

Exclusion criteria

none

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2017
Enrollment:	96
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5806
NTR-old	NTR5961
Other	ABR-nummer van de CCMO : 57503

Study results

Summary results

Human Reprod 2019. Low prevalence of male microchimerism in women with MRKH