

The Randomised Uterine Septum Transsection Trial

Published: 03-11-2008

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This study will answer the question whether surgical intervention (metroplasty) in women with recurrent miscarriage and/or subfertility and a septate uterus will improve their reproductive outcome.

Ethical review	-
Status	Recruitment stopped
Health condition type	Abortions and stillbirth
Study type	Interventional

Summary

ID

NL-OMON37108

Source

ToetsingOnline

Brief title

TRUST

Condition

- Abortions and stillbirth
- Congenital reproductive tract and breast disorders
- Obstetric and gynaecological therapeutic procedures

Synonym

septate uterus, uterine septum

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: hysteroscopic septoplasty, recurrent miscarriage, septate uterus, subfertility

Outcome measures

Primary outcome

Primary outcome is live birth rate in each treatment group.

Secondary outcome

Secondary outcomes are complications following hysteroscopic metroplasty; uterine perforation, fluid overload, endometritis, clinical pregnancy and miscarriage. In a subsequent pregnancy, we will look at the prevalence of adversary pregnancy outcomes, placental abruption, premature delivery, uterine rupture, and mode of delivery (vaginal vs. caesarean section).

Study description

Background summary

It is recognized that the prevalence of the septate uterus is increased in women with recurrent miscarriage.

At present the finding of a septate uterus in women with recurrent miscarriage is not an indication for surgical correction of the septum.

The role of hysteroscopic metroplasty in patients with a septate uterus and subfertility has neither been evaluated properly. The current literature regarding the incidence and probable causes of subfertility among women with congenital uterine anomalies is insufficient to allow any robust conclusions to be drawn.

Whether hysteroscopic metroplasty should be performed in this group of patients to improve fecundity is subject of debate.

It is questionable whether hysteroscopic metroplasty in women with recurrent miscarriage and or subfertility will improve their reproductive outcome.

Study objective

This study will answer the question whether surgical intervention

(metroplasty) in women with recurrent miscarriage and/or subfertility and a septate uterus will improve their reproductive outcome.

Study design

Randomized controlled trial.

Intervention

Random allocation to hysteroscopic metroplasty or no intervention.

Study burden and risks

We will compare expectant management with surgical intervention. The intervention under research is a commonly practiced and safe operative procedure in gynaecology, but it is not known whether it is efficacious. The risk and burden of participation is the risk of known complications following hysteroscopy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

The trial will study women with a history of recurrent miscarriage or pregnancy loss before 20 weeks of gestational age and/or subfertility and a septate uterus. Recurrent miscarriage is defined as two or more, not necessarily consecutive, pregnancy losses before 20 weeks of gestational age. Subfertility is defined as the inability to conceive for a minimal period of one year. Only women with an active wish to conceive will be eligible.

Exclusion criteria

Prior inclusion in the TRUST study.

Contraindications for surgery.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2010
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO

Date: 17-11-2011

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: 27552

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL24082.018.08
OMON	NL-OMON27552

Study results

Date completed: 28-10-2018

Actual enrolment: 67

Summary results

Trial is ongoing in other countries