

# The Randomised Uterine Septum Transsection Trial.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27552

### Source

Nationaal Trial Register

### Brief title

TRUST

### Health condition

septate uterus  
recurrent miscarriage  
hysteroscopic metroplasty  
metroplasty  
uterine anomalies

uterus septum  
uterusanomalieën  
herhaalde miskraam  
septumtranssectie

## Sponsors and support

**Primary sponsor:** Academic Medical Centre, Amsterdam

**Source(s) of monetary or material Support:** fund=initiator=sponsor

## Intervention

## Outcome measures

### Primary outcome

Live birth rate (defined as a live birth after 24 weeks of gestational age).

### Secondary outcome

1. Complications following hysteroscopic metroplasty;
2. Obstetrical complications.

## Study description

### Background summary

It is recognized that the prevalence of the septate uterus is increased in women with recurrent miscarriage and subfertility. At present the finding of a septate uterus in women with an active wish to conceive is not an indication for surgical correction of the septum (metroplasty). It is questionable if metroplasty will improve reproductive outcome in these patients.

Objective: This study aims to answer the question whether hysteroscopic metroplasty will improve reproductive outcome in women with recurrent miscarriage or subfertility and a septate uterus.

### Study objective

Metroplasty in women with recurrent miscarriage or subfertility and a septate uterus will improve reproductive outcome.

### Study design

No interim analysis has been planned.

### Intervention

Hysteroscopic metroplasty.

## Contacts

### Public

Fertility doctor/PhD student <br>  
Center for Reproductive Medicine<br>  
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### Scientific

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## Eligibility criteria

### Inclusion criteria

- Suspicion of a septate uterus
- Active wish to conceive
- (Recurrent) miscarriage, subfertility or preterm birth
- Diagnosis of a septate uterus

### Exclusion criteria

1. Prior randomisation in the TRUST;
2. Contraindications for surgery.

## Study design

## Design

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

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2008
Enrollment:	68
Type:	Actual

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	18-02-2009
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 37108  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL1596
NTR-old	NTR1676
CCMO	NL24082.018.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON37108

## Study results

### Summary results

N/A