

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

To assess whether hysteroscopic metroplasty will improve reproductive outcome in infertile women with a septate uterus and an active wish to conceive

Protocol summary

Summary

A septate uterus is a uterine anomaly that affects reproductive outcome. Women with a septate uterus are at risk for recurrent miscarriage, subfertility and preterm birth. Resection of the septum is subject of debate. There is no convincing evidence concerning its effectiveness and safety. This study will assess whether hysteroscopic metroplasty will improve reproductive outcome in women with a septate uterus. This is multicenter randomised controlled trial under the supervision of Academisch Medisch Centrum Amsterdam in which 68 women with a septate uterus with an active wish to conceive are randomly allocated to hysteroscopic metroplasty(intervention group) or expectant management (control group). Primary outcome is live birth defined as the birth of a living foetus beyond 34 weeks of gestation. Secondary outcomes are ongoing pregnancy, clinical pregnancy, miscarriage, pregnancy outcomes as placental abruption, uterine rupture, preterm birth and mode of delivery (vaginal versus caesarean section), perinatal morbidity and mortality and complications following metroplasty, such as uterine perforation, fluid overload and endometritis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112331052N1**
Registration date: **2017-03-08, 1395/12/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-08, 1395/12/18

Registrant information

Name

Roya Padmehr

Name of organization / entity

Avicenna Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2351 9390

Email address

r.padmehr@ari.ir

Recruitment status

Recruitment complete

Funding source

Avicenna Research Center

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To assess whether hysteroscopic metroplasty will improve reproductive outcome in infertile women with a septate uterus and an active wish to conceive

Public title

The Randomised Uterine Septum Transsection Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women who visited in Avicenna Research center and 6 medical centers in netherland ;

The trial will include women with a septate uterus and an active wish to conceive. A septate uterus is defined as a uterus with a division (septum) of the uterine cavity, without any restrictions to the length of the septum. The external contour of the uterus should not have an indentation; Having satisfaction about participating in this study . Exclusion criteria: Women with contraindication for surgery

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Avicenna Research Center

Street address

Avicenna Research Center, Shahid Beheshti University

City

Tehran

Postal code

1936773493

Approval date

2016-10-30, 1395/08/09

Ethics committee reference number

1395.2.IR.ACECR.REC

Health conditions studied

1

Description of health condition studied

Septated Uterus

ICD-10 code

q51.9

ICD-10 code description

Congenital malformation of uterus and cervix, unspecified

Primary outcomes

1

Description

Live birth after 24 weeks pregnancy

Timepoint

Live birth at least 24 weeks of gestational age within one year after surgery

Method of measurement

Sonography and clinical visits and notes

Secondary outcomes

1

Description

Uterine perforation during intervention

Timepoint

During hysteroscopic metroplasty of septated uterus

Method of measurement

Clinical findings, hysteroscopic findings, sonographic findings

2

Description

Abortion

Timepoint

Within one year of intervention

Method of measurement

Clinical findings

3

Description

Week of pregnancy that abortion occurred

Timepoint

Within 1 years after intervention

Method of measurement

Week of pregnancy

4

Description

Uterine perforation in pregnancy after intervention

Timepoint

During pregnancy within one year of intervention

Method of measurement

Clinical findings

5

Description

Preterm labor

Timepoint

Within one year of intervention

Method of measurement

Weeks of pregnancy

6

Description

Clinical pregnancy

Timepoint

Within 1 years after intervention

Method of measurement

Sonography

7

Description

Endometritis

Timepoint

Till 6 weeks after intervention

Method of measurement

Clinical findings

8

Description

Maternal death during pregnancy

Timepoint

Within one year after intervention

Method of measurement

Clinical findings

Intervention groups

1

Description

Intervention: Hysteroscopic metroplasty in patients who have septated uterus and wishing to have pregnancy. In patients with uterine septum and wishing to have pregnancy, hysteroscopic uterine septum resection will be done.

Category

Treatment - Surgery

2

Description

Control: women with wishing to pregnancy and having septated uterus but we will not perform hysteroscopic septum resection for them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Avicenna Infertility Center

Full name of responsible person

Roya Padmehr

Street address

Avicenna Infertility Center, Yakhchal street, Shariati

avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Avicenna Research Center

Full name of responsible person

Roya Padmehr

Street address

Avicenna Infertility Center, Yakhchal street, Shariati avenue

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Avicenna Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Avicenna research center

Full name of responsible person

Roya Padmehr

Position

Obstetrician and Gynecologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty