Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 satiafaction 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 intervetion

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 occured

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
Within1 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
Street address
Avicenna infertility center,Yakhchal street, Shariati avenue
City
Tehran
Postal code
1936773493
Phone
+98 21 23519
Fax
+98 21 2264 4754
Email
r.padmehr@ari.ir
Web page address

Person responsible for scientific 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

Street address
Avicenna infertility center, Yakhchal street, Shariati avenue

City
Tehran

Postal code
1936773493

Phone
+98 21 23519

Fax
+98 21 2264 4754

Email
r.padmehr@ari.ir k.shadjoo@ari.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Avicenna Research Center

Full name of responsible person
Roya Padmehr

Position
Obstetrician and Gynecologist

Other areas of specialty/work

Street address
Avicenna infertility center, Yakhchal street, Shariati avenue

City
Tehran

Postal code
1936773493

Phone
+98 21 23519

Fax
+98 21 2264 4754

Email
r.padmehr@ari.ir k.shadjoo@ari.ir

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