

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the incidence of intrauterine adhesions after hysteroscopic removal of the uterine septum in a patient with metritis and its relationship with the size of the septum and the surgical method (resectoscope and scissors)

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the incidence and severity of uterine rupture after hysteroscopic removal of the uterine septum and determining its relationship with septal size

Design

A clinical trial with a control group, with parallel, randomized, phase 3 groups, is performed on 400 patients. Randomization is based on a table of computer random numbers.

Settings and conduct

Hysteroscopy is performed in the operating room of the gynecology ward of Imam Reza (AS) Hospital by the Olympus hysteroscope. The size of the septum (short or long) and its type (wide or narrow) are recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All women who were candidates for septum removal based on hysterosalpingography, MRI or sonohysterography with diagnosis of uterine septum, informed consent. exclusion criteria : not completing the consent form, having an underlying disease

Intervention groups

hysteroscopy is performed in the operating room of the women's department of Imam Reza Hospital (AS) by Olympus hysteroscope. And during that, the septum is removed with hysteroscopy scissors with a resectoscope with a monopolar L shape electrode and glycine media.

Main outcome variables

Determination of incidence and severity

Last update: **2022-10-01, 1401/07/09**

Update count: **0**

Registration date

2022-10-01, 1401/07/09

Registrant information

Name

Maliheh Amirian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 315 6170

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the incidence of intrauterine adhesions after hysteroscopic removal of the uterine septum in a patient with metritis and its relationship with the size of the septum and the surgical method (resectoscope and

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220420054595N1**

Registration date: **2022-10-01, 1401/07/09**

scissors)

Public title
Intrauterine adhesion after removed hysteroscopic

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of uterine septum diagnosis Patient satisfaction with entering the plan
Exclusion criteria:
Observation of another pathology intrauterine in addition to the septum, during hysteroscopy Patient with postoperative metritis The presence of an underlying disease that increases the risk of uterine infection.

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **500**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants in the study are assigned to two intervention and control groups by simple randomization method, with individual units and using a table of random numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Department of Obstetrics and Gynecology, Imam Reza Hospital, Imam Reza Square.

City

Mashad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2015-10-07, 1394/07/15

Ethics committee reference number

IR.MUMS.fm.REC.1394.353

Health conditions studied

1

Description of health condition studied

Intrauterine synechiae

ICD-10 code

N85.6

ICD-10 code description

Intrauterine synechiae

Primary outcomes

1

Description

intrauterine adhesion

Timepoint

3 months after surgery

Method of measurement

checked up

2

Description

Severity of intrauterine adhesion

Timepoint

3 months after surgery

Method of measurement

Based on FIGO classification

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The septum is removed with hysteroscopic scissors with a monopolar L-shaped electrode and glycine media.

Category

Diagnosis

2

Description

Control group: The septum is removed with hysteroscopic scissors with normal saline media.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Maliheh Amirian

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Department of Obstetrics and Gynecology, Imam Reza Hospital, Shariati Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology of Medical Sciences of Mashhad

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Golrokh Sharafati

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Position

resident

Latest degree

Specialist

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available