

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of two different Estrogen doses in prevention of synechia after hysteroscopic treatment of Asherman syndrom patients

Protocol summary

Study aim

evaluation and comparison of the effect of two different Estrogen doses in prevention of synechia after hysteroscopic treatment of Asherman syndrome patients

Design

60 patients with moderate to severe Asherman syndrome who refer to gynecology clinic of Imam Reza Hospital, after Hysteroscopic resection of synechia based on inclusion criteria, will be randomly divided to two groups of 30 people.

Settings and conduct

Concern about high risk of synechia recurrence after surgical hysteroscopic treatment of Asherman syndrome and also no consensus on appropriate Estrogen dose after surgery to effectively lead to creation of endometrium and prevent the recurrence of synechia are the reasons of this study. This study will be done on patients with moderate to severe Asherman syndrome referring to gynecology clinic of Imam Reza Hospital. Based on a randomization table provided by a computer, these patients are divided to two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all symptomatic patients (infertility or cyclic pelvic pain) referring to gynecology clinic of Imam Reza Hospital who are diagnosed with moderate to severe Asherman syndrome, after acquisition of consent will be included in the study. Exclusion criteria: another pathology in pelvic exam -history of Uterine myoma or gynecology cancer -hormone consumption during past month-history of genital tuberculosis and -contraindication for hormone therapy.

Intervention groups

Control group receives conjugated Estrogen with 2.5 milligram dose daily and intervention group receives 5 milligram dose (through two doses) for 40 days. In the last 10 days, 10 milligram of Medroxyprogesteron will also be daily prescribed.

Main outcome variables

frequency and intensity of synechia, frequency of people

with amenorrhea and hypomenorrhea, frequency of infertility, frequency of miscarriage and intensity of pelvic pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141230020486N3**

Registration date: **2018-02-04, 1396/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-04, 1396/11/15**

Update count: **0**

Registration date

2018-02-04, 1396/11/15

Registrant information

Name

Leili Hafizi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2608

Email address

hafizil@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research center of Mashhad University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two different Estrogen doses in prevention of synechia after hysteroscopic treatment of Asherman syndrom patients

Public title

Comparison of two different Estrogen doses in prevention of synechia after hysteroscopic treatment of Asherman syndrom patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

all symptomatic patients (infertility or cyclic pelvic pain) referring to gynecology clinic of Imam Reza Hospital who are diagnosed with moderate to severe Asherman syndrome.

Exclusion criteria:

Another pathology in pelvic exam History of Uterine myoma or gynecology cancer hormone consumption during past month History of genital tuberculosis contraindication for hormone therapy

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done through a randomization table provided by a computer. In order to conceal the randomized allocation of the two groups, sealed and numbered envelopes will be used. When a patients refer, envelopes are opened and the treatment methods will be determined.

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

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2016-12-15, 1395/09/25

Ethics committee reference number

IR.MUMS.fm.REC.1395.365

Health conditions studied**1****Description of health condition studied**

Asherman syndrome

ICD-10 code

N85.6

ICD-10 code description

Intrauterine synechiae

Primary outcomes**1****Description**

Percentage of people who face recurrence of synechia after treatment of Asherman syndrom

Timepoint

2 months after using of estrogen

Method of measurement

After treatment period and and bleeding are over, all patients will again go through hysteroscopy and uterine cavity condition will be investigated.

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: after surgery, patients receives Estrogen with 2.5 milligram dose daily for 40 days. In the last 10 days,10 milligram of Medroxyprogesteron will also be daily prescribed.

Category

Treatment - Drugs

2

Description

Intervention group: after surgery, patients receives 5 milligram dose (through two doses) for 40 days. In the last 10 days, 10 milligram of Medroxyprogesterone will also be daily prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Leili Hafizi

Street address

Emam Reza Sq, Ebne-sina Ave, Emam Reza hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

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

Dr Leili Hafizi

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Position

Associated Professor

Latest degree

Specialist

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after patients are made unidentifiable.

When the data will become available and for how long

The data can be accessible for specific organization request 6 month after the article is published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

In case those people asking for data have the intention of optimizing the study a data and producing more results, access to data is allowed.

From where data/document is obtainable

Through sending an email to the corresponding author, data will be obtainable.

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments