Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 citeria, 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 Esterogen 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 Medroxyprogestron 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 Medroxyprogestron 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 Medroxyprogestron 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
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2608
Email
hafizil@mums.ac.ir

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
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3841 2081
Email
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
Street address
Emam Reza Sq. Ebne-sina Ave, Emam Reza hosital
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2608
Fax
Email
hafizil@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Leili Hafizi
Position
Associated Proffesor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Emam Reza Sq. ebne-sina Ave, Emam Reza hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone

+98 51 3802 2608

Fax

Email

hafizil@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Leili Hafizi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2608

Fax

Email

hafizil@mums.ac.ir

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