

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of hormone therapy alone with hormone therapy and platelet-rich plasma in the improvement of Asherman's syndrome after hysteroscopy in educational centers of Isfahan University of Medical Sciences

Protocol summary

Study aim

Comparison of the effectiveness of hormone therapy alone with hormone therapy with platelet-rich plasma in the improvement of Asherman's syndrome after hysteroscopy in educational centers of Isfahan University of Medical Sciences

Design

After the definitive diagnosis of the disease and obtaining informed consent, the demographic information of the patients, including age and midwifery information, menstrual rate, etc., is recorded and the patients who have entry criteria are divided into two groups. The severity of intrauterine adhesions is determined by clinical evidence and hysteroscopic findings. For the first group, hormone therapy alone, and for the second group, platelet-rich hormone therapy will be performed after hysteroscopy. In the control group, after hysteroscopy and removal of adhesions, they are treated only with hormone therapy. Finally, patients in both groups were examined hysteroscopically after 6 to 8 weeks later for recurrence and adhesion.

Settings and conduct

Educational centers of Isfahan University of Medical Sciences in 1398

Participants/Inclusion and exclusion criteria

Entrance: 1- Clinical diagnosis of Asherman's syndrome; 2- Age 18 to 43 years; 3- Conscious consent to participate in the study. Exit: 1- Age less than 18 and more than 43 years; 2- Simultaneous infection of the uterus and vagina; 3- Hemoglobin less than 11; 4- Platelet less than 150,000; 5 - History of anticoagulant use; 6- Dissatisfaction with entering the study.

Intervention groups

PRP and hormone therapy

Main outcome variables

Type of treatment; uterine adhesion grade; menstrual

period; BMI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200316046789N1**

Registration date: **2022-02-11, 1400/11/22**

Registration timing: **retrospective**

Last update: **2022-02-11, 1400/11/22**

Update count: **0**

Registration date

2022-02-11, 1400/11/22

Registrant information

Name

Mahdi Hadian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3568 8890

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

2020-03-20, 1399/01/01

Actual recruitment end date

2021-09-22, 1400/06/31

Trial completion date

2021-09-22, 1400/06/31

Scientific title

Comparison of the effectiveness of hormone therapy alone with hormone therapy and platelet-rich plasma in the improvement of Asherman's syndrome after hysteroscopy in educational centers of Isfahan University of Medical Sciences

Public title

Evaluation of the effectiveness of platelet-rich plasma in the treatment of Asherman's syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Clinical diagnosis of Asherman's syndrome Age: 18 to 43 years old Informed consent to participate in the study

Exclusion criteria:

Simultaneous infection of the uterus and vagina
Hemoglobin less than 11 Platelet less than 150,000
History of anticoagulant use Dissatisfaction with entering the study

AgeFrom **18 years** old to **43 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60**Actual sample size reached: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

After definitive diagnosis and informed consent, patients are divided into two groups based on the time of referral. The selection of patients in two groups is completely random.

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 Isfahan University of Medical Sciences

Street address

Hezar Jerib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-03-09, 1398/12/19

Ethics committee reference number

IR.MUI.MED.REC.1398.671

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**

Uterine adhesion grade

Timepoint

6 to 8 weeks later hysteroscopy

Method of measurement

Hysteroscopy

Secondary outcomes

empty

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

Intervention group:case (PRP and hormone therapy group) (n = 30/each groups). The selection of patients in two groups was completely random. 8.5 ml of peripheral venous blood of patient was taken through a syringe containing 1.5 ml of citrate acid. It was then centrifuged immediately at 1000 g for 10 min. The buffy coat layer and the plasma layer were collected and transferred to another tube to be centrifuged again at 3500 g for 5 min. 1.5 ml of PRP with a good concentration were finally obtained.To perform the plan for patients in the case group, after removal of the adhesion by hysteroscopy, PRP 1ml is injected into the uterine cavity wall . They are then given hormone therapy, the usual regimen is 2.5 mg of conjugatedestrogen once a day for four weeks.A progestin such as medroxyprogesterone acetate at a

dose of 10 mg is added to the treatment in the last week. Finally, 6 to 8 weeks later patients in both groups were examined hysteroscopically. The intrauterine adhesion grade and menstruation pattern before and after the intervention were evaluated.

Category

Treatment - Drugs

2**Description**

Control group: control (hormone therapy)(n = 30/each groups) In the control group, after hysteroscopy and removal of adhesions, they are treated only with hormone therapy. They are then given hormone therapy, the usual regimen is 2.5 mg of conjugated estrogen once a day for four weeks. A progestin such as medroxyprogesterone acetate at a dose of 10 mg is added to the treatment in the last week. Finally, 6 to 8 weeks later patients in both groups were examined hysteroscopically. The intrauterine adhesion grade and menstruation pattern before and after the intervention were evaluated.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Zahra Derakhshandeh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Derakhshandeh

Position

resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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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 people have not been identified

When the data will become available and for how long

Start of access period from 1399

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For future researches

From where data/document is obtainable

09133057797 Dr. Zahra Derakhshandeh

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

Contact the project executor Send documents Receive data

Comments