

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Investigation of the effect of intrauterine hyaluronic acid on the prevention of Asherman's syndrome in cases of endometrial injury in patients with septal resection surgery

Protocol summary

Study aim

The purpose of the present study was to investigate the impact of intrauterine injection of hyaluronic acid in the prevention of Asherman's syndrome in patients with endometrial septal resection.

Design

The clinical trial with parallel groups, double blinded, randomized

Settings and conduct

Subjects are recruited according to the criteria for entering the study from among the patients who are candidates for septal resection referring to Shahid Sadoughi Hospital in Yazd. Patients will be divided into two groups: intervention and placebo, and the random number table are used for randomization. In the intervention group, 1 cc of hyaluronic acid gel is injected, and in the placebo group, 1 cc of normal saline solution is injected as a placebo inside the uterine cavity. Hyaluronic acid and normal saline gels are prepared and coded in the same syringes in the same volume so that neither the patient nor the researcher (the assistant who enters the information in the questionnaire) knows what group the patient is in.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidates for uterine septal resection surgery who have suffered endometrial damage during surgery, age 15- 45 years Exclusion criteria: BMI > 35, menopause, pregnancy, cervical cancer, coagulation disorder, infections inside the pelvis, unwillingness for participation in study

Intervention groups

In the intervention group, 1 cc of hyaluronic acid gel (humedix- produced in South Korea) and in the placebo group, 1 cc of normal saline solution is injected into the uterine cavity.

Main outcome variables

Intrauterine adhesions, Asherman's syndrome, menstrual

bleeding, number of menstrual days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046993N1**

Registration date: **2020-04-16, 1399/01/28**

Registration timing: **retrospective**

Last update: **2020-04-16, 1399/01/28**

Update count: **0**

Registration date

2020-04-16, 1399/01/28

Registrant information

Name

Atiyeh Javaheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3183 4284

Email address

a.javaheri@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-04, 1398/08/13

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

2019-11-04, 1398/08/13

Actual recruitment end date

2019-12-22, 1398/10/01

Trial completion date

2020-02-19, 1398/11/30

Scientific title

Investigation of the effect of intrauterine hyaluronic acid on the prevention of Asherman's syndrome in cases of endometrial injury in patients with septal resection surgery

Public title

Evaluation of the effect of hyaluronic acid in the prevention of Asherman's syndrome.

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidates for uterine septal resin surgery who have suffered endometrial damage during surgery. Age 15-45 years

Exclusion criteria:

BMI > 35 kg/m² Menopause Pregnancy Cervical cancer Coagulation disorder Severe pelvic infections People who do not willing to cooperate after explaining the work.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **65**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method with individual unit and Random number table was used for randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Hyaluronic acid and normal saline gels were prepared and coded in similar syringes all with the same volume, and the entire injections were performed by one person (Obstetrics & Gynecology resident). All participants and project executives were blinded to group information; neither the patient nor the researcher collecting the data knew about the type of solution and group classification. Randomization and allocation were concealed from the investigators and study participants until the completion of analyses.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid sadoughi University Of Medical Sciences

Street address

Bahonar Sq., Shahid Sadoughi Ave., Shahid Sadoughi University of Medical Sciences, Yazd

City

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Province

Yazd

Postal code

8916978477

Approval date

2019-11-03, 1398/08/12

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.201

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**

Intrauterine adhesions

Timepoint

Two times, before and 2 months after intervention

Method of measurement

Hysteroscopy and American Society of Reproductive Medicine scoring system

2**Description**

Volume of menstrual bleeding

Timepoint

Two times, before and 2 months after intervention

Method of measurement

Questionnaire

3**Description**

Number of menstrual days

Timepoint

Two times, before and 2 months after intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

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

Intervention group: Injection of 1 cc of hyaluronic acid gel into the uterine cavity

Category

Prevention

2**Description**

Control group: Injection of 1 cc of normal saline solution as a placebo into the uterine cavity

Category

Placebo

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

Yazd Shahid Sadoughi hospital

Full name of responsible person

Atiyeh Javaheri

Street address

Ebne- Sina Ave., Shahid Ghandi Blvd., Shahid Sadoughi hospital

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a.javaheri@ssu.ac.ir

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

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

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mmirzaei@ssu.ac.ir

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

Yes

Title of funding source

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Atiyeh Javaheri

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Atiyeh Javaheri

Position

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Latest degree

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Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Atiyeh Javaheri

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

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