Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 resin 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)

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+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
Yazd
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
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Bahonar Sq., Shahid Sadoughi Ave., Shahid Sadoughi University of Medical Sciences, Yazd
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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 updating data

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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