

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Determine the effect of hyaluronic acid gel on the hysteroscopic outcomes following surgical removal of intra-uterine adhesions

Protocol summary

Summary

The patients who had eligible criteria randomly divided in two groups 43 patients in each group. Scoring of intra uterine adhesion was done by (ASRM) score, which include hysteroscopic results and clinical symptoms. Study condition and probable side effect of Hyaluronic acid gel were explained for all cases who had eligible criteria. For this study a questionnaire was designed which include demographic data, Lab & check up results before and after treatment. After getting consent, data gathered by questionnaire the cases were undergone hysteroscopy and intrauterine adhesion was determined by ASRM score. Then uterine cavity expanded by saline normal 0.9%. 10 CC Hyaluronic acid gel injected in the uterine cavity in case group, but no injection in control group. In both case and control group Cephasoline was injected during procedure. All the cases and controls were undergone diagnostic hysteroscopic for 4 to 6 weeks after intervention to evaluate intrauterine adhesion by ASRM score.

General information

Acronym

(HGS)

IRCT registration information

IRCT registration number: **IRCT201703057513N14**

Registration date: **2017-10-07, 1396/07/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-07, 1396/07/15

Registrant information

Name

Hatav Ghasemi Tehrani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research Of Preventive Gynecology
Research Center Of Shahid Beheshti Medical School

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determine the effect of hyaluronic acid gel on the hysteroscopic outcomes following surgical removal of intra-uterine adhesions

Public title

Determine the effect of hyaluronic acid gel on the hysteroscopic outcomes following surgical removal of intra-uterine adhesions in women referred to the taleghani clinic of ShahidBeheshti university of medical sciences in Tehran in 1394-95

Purpose

Treatment

Inclusion/Exclusion criteria

Including criteria: intrauterine adhesion according to 3D sonography; sonohysterography; hysterosalpingography;

hysteroscopy. Excluding criteria: unsatisfaction; age more than 50; weight more than 100 kg; menopause; pregnancy; malignancy; coagulopathy

Age

From **18 years** old to **46 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **43**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Etical comitee of SHAHID BEHESHTI MEDICAL SCHOOL

Street address

Shahid Beheshti Medical University ,Aarabee Street
,University square,Velengac,Tehran

City

TEHRAN

Postal code

81668

Approval date

2017-03-05, 1395/12/15

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.1007

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

Adhesion scoring

Timepoint

4 to 6 weeks after hysteroscopy

Method of measurement

With hysteroscopy & ASRM score

Secondary outcomes

1

Description

Pregnancy Rate

Timepoint

After action for pregnancy

Method of measurement

B HCG

Intervention groups

1

Description

Adhesion release and hyaluronic gel injection genewel
company (10cc=5gr) commercial name =Guardix

Category

Treatment - Surgery

2

Description

Adhesion release without gel injected

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital & Shohaday Tajrish Hospital

Full name of responsible person

Leila Nazari

Street address

Shohadaye Tajrish Hospital, Tajrish Square,
Tehran,Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti Medical School

Full name of responsible person
Hataf Ghasemi Tehrani

Street address
Taleghani hospital, Aarabi Street, Velengak, Tehran

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti Medical School

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Isfahan Medical School

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Position
Assitant Professor Of OB & GYN

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty