

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of transplantation of bone marrow, adipose, and endometrial stem cells on endometrium structure and fertility in Ashermans syndrom and endometrial atrophy

Protocol summary

Study aim

Comparison the effects of transplantation of bone marrow, adipose, and endometrial stem cells on endometrium structure and fertility in Ashermans syndrome and endometrial atrophy

Design

Non-controlled quasi-clinical trials. Sampling method: convenient sampling. Randomized method: in this study, measurements will be performed before and after the intervention, so there will be no randomization. Blinding: blinding will not be performed in this study because only one group will be sampled and the analysis will be compared before and after:

Settings and conduct

In this prospective non-controlling clinical trial, infertile patients referred to the infertility department of of Hamedan University of Medical Sciences who suffer from Asherman syndrome or thin endometrium and have no response to other treatments will be included in this study. Before starting, we will obtain consent form patient for biopsy and transplantation. 2-Diagnosis of Asherman syndrome and thin endometrium by hysteroscopy and its grading. 3-Determining the thickness of the endometrium by ultrasound and removing endometrial biopsy from the uterus and the fundus using curettage in the proliferative phase . 4- Isolation of mesenchymal cells from bone marrow, adipose tissue, or uterine endometrium (based on the results of an animal study) 5- Cell transplantation 6- Recording the severity and length of menstrual period. 7_ Three month following the transplantation, ultrasound, hysteroscopy and endometrial biopsy will be done for histological examination. 8- Determination of adhesion and thickness of the endometrium by sonography and hysteroscopy

Participants/Inclusion and exclusion criteria

Infertile women with Asherman syndrome and thin

endometrium who have not responded to surgical and hormonal treatments.

Intervention groups

Mesenchymal stem cells

Main outcome variables

Endometrium thickness and fibrosis; fertility percent

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190306042948N1**

Registration date: **2019-04-15, 1398/01/26**

Registration timing: **prospective**

Last update: **2019-04-15, 1398/01/26**

Update count: **0**

Registration date

2019-04-15, 1398/01/26

Registrant information

Name

Sara Soleimani Asl

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 81 3838 0023

Email address

s.soleimanasl@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2021-05-22, 1400/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Effects of transplantation of bone marrow, adipose, and endometrial stem cells on endometrium structure and fertility in Ashermans syndrom and endometrial atrophy

Public title
Stem cell- based therapy in Asherman syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile patients referred to the Fatemieh infertility department of Hamadan University of Medical Sciences who suffer from Asherman syndrome or thin endometrium and did not respond to common treatments such as hormone therapy and surgery.
Exclusion criteria:
Patients with cardiovascular, renal disorders Patients with Syphilis, Hepatitis, AIDS Patients with husband infertility factor Endometrial thickness more than 7 mm

Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information

Sample size
Target sample size: **10**
Randomization (investigator's opinion)
N/A

Randomization description
Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Shahid Fahmideh BLV. Hamadan University of Medical Sciences
City
Hamadan
Province
Hamadan
Postal code
6517865178
Approval date
2019-02-22, 1397/12/03
Ethics committee reference number
IR.UMSHA.REC.1397.865

Health conditions studied

1

Description of health condition studied
Asherman Syndrome
ICD-10 code
N97.2
ICD-10 code description
Female infertility of uterine origin

2

Description of health condition studied
Endometrial Atrophy
ICD-10 code
A97.2
ICD-10 code description
Female infertility of uterine origin

Primary outcomes

1

Description
Endometrial thickness
Timepoint
Before transplantation and every month for one year after cell therapy
Method of measurement
Ultrasonography

2

Description
Menstruation
Timepoint
Monthly for one year after transplantation
Method of measurement
Number of menstruation days and used pads

3

Description
Fertility percent
Timepoint
For one year following transplantation
Method of measurement

Routine pregnancy tests

Secondary outcomes

1

Description

FSH

Timepoint

Before and three months following cell transplantation

Method of measurement

Blood sampling

2

Description

LH

Timepoint

Before and three months following cell transplantation

Method of measurement

Blood sampling

3

Description

Endometrial adhesion

Timepoint

Before and three month after cell transplantation

Method of measurement

Ultrasonography

Intervention groups

1

Description

Intervention group: Single Stem cells transplanted cell (10000000 cells)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital of Hamadan University of Medical Sciences

Full name of responsible person

Sara Soleimani Asl

Street address

Fertility and Infertility center, Fatemieh Hospital, Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

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Shahid Fahmideh BLV. Research and Technology Vice- chancellors, Hamadan University of Medical Sciences

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Sara Soleimani Asl

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Other areas of specialty/work
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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

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

Title and more details about the data/document

After the completion of the study, information on the main results will be shared.

When the data will become available and for how long

After the online publication of the results in the authoritative journal

To whom data/document is available

Researchers and investors in the private sector

Under which criteria data/document could be used

Further study by researchers, an investigation by investors for potential investment in cell therapy

From where data/document is obtainable

Dr. Sara Soleimani Asl sr_soleimani@yahoo.com
+989144529036

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

Please send your application to the above-mentioned email address, you will receive requested information for less than one month.

Comments