

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessment of safety and effectiveness of intrauterine infusion of allogeneic menstrual blood stem cells in women with unexplained recurrent pregnancy loss: A double-blind phase 1 and 2 clinical trial

#### Protocol summary

##### Study aim

Assessment of safety and effectiveness of intrauterine infusion of allogeneic menstrual blood stem cells in patients with unexplained recurrent pregnancy loss

##### Design

A randomized, double-blind, sham-controlled phase 1&2 clinical trial with forty patients, followed for one year

##### Settings and conduct

Recurrent pregnancy loss is one of the common disorders of pregnancy. In this clinical trial, effect of intrauterine infusion of allogeneic decidualized menstrual blood stem cells in women with unexplained recurrent pregnancy loss will be assessed. In this project, which is conducted in Avicenna infertility clinic, 40 women with recurrent pregnancy loss will randomly be divided into two groups of 20. Women in treatment group will receive intrauterine infusion of allogeneic decidualized menstrual blood stem cells, while in control women intrauterine sterile PBS buffer will be infused. Menstrual blood stem cells will be obtained from AIC stem cell bank. Cells will be decidualized in vitro for 6 days. Participants and clinicians are not aware of intervention type

##### Participants/Inclusion and exclusion criteria

In this project, women with recurrent pregnancy loss are recruited. Women with past history of pregnancy are not recruited.

##### Intervention groups

Forty women with unexplained recurrent pregnancy loss are randomly divided into two groups of 20 (treatment and control). Women in treatment group will receive intrauterine infusion of allogeneic decidualized menstrual blood stem cells, while in control women intrauterine sterile PBS buffer will be infused

##### Main outcome variables

Side effects of intrauterine infusion of allogeneic decidualized menstrual blood stem cells, percent of abortion, percent of clinical pregnancy, live birth rate,

frequency of twins birth, weight of newborn

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210513051280N2**

Registration date: **2021-05-31, 1400/03/10**

Registration timing: **prospective**

Last update: **2021-05-31, 1400/03/10**

Update count: **0**

##### Registration date

2021-05-31, 1400/03/10

##### Registrant information

##### Name

AMIR-HASSAN ZARNANI

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 2020

##### Email address

zarnania@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-21, 1400/04/30

##### Expected recruitment end date

2022-02-19, 1400/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Assessment of safety and effectiveness of intrauterine infusion of allogeneic menstrual blood stem cells in women with unexplained recurrent pregnancy loss: A double-blind phase 1 and 2 clinical trial

**Public title**

Evaluation of the effect of menstrual blood stem cells in recurrent pregnancy loss

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women with primary recurrent pregnancy losses (at least two successive pregnancy losses excluding blighted ovum confirmed by sonography or pathology till 10th week of gestation Maximum patient age: 37 years, no history of previous live birth FSH level of less than 10 mIU/mL Negative test results for HIV, HBS Ag, HCV and VDRL

**Exclusion criteria:**

Having previous history of successful pregnancy Chromosomal abnormalities in parents Uterine anatomic abnormalities Hormonal abnormalities PCO with metabolic syndrome Uncontrolled diabetes Stage 3 or 4 endometriosis Autoimmune diseases including rheumatoid arthritis, thyroid autoimmunity, lupus and anti-phospholipid antibodies History of cancer, chemotherapy and radiotherapy Spermogram abnormalities (DFI more than 30 and normal sperm morphology less than 2% History of immunosuppressive drugs intake including corticosteroids during the past three months

**Age**

From **20 years** old to **37 years** old

**Gender**

Female

**Phase**

1-2

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization: In order to randomly assign 40 subjects in treatment group or control group, 10 blocks including 4 subjects each will be defined using "https://app.studyrandomizer.com". Blocks are small and balanced with predetermined group assignments, which keeps the numbers of subjects in each group similar at all times. Treatment group and control group will be identified by codes A and B, respectively. In each block, number of treatment group and control group is equal with assigning ratio of 1:1.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Neither participants nor clinical care or analyzers are aware of the type of intervention

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Academic Center for Education, Culture and Research (ACECR)- biomedical research ethics committee

**Street address**

No.1270, Secretariat of the Ethics Committee of ACECR, Deputy of Research and Technology, Headquarter of ACECR, Opposite the main door of Tehran University, Enghelab street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

4364 - 14155

**Approval date**

2021-03-15, 1399/12/25

**Ethics committee reference number**

IR.ACECR.REC.1399.007

**Health conditions studied****1****Description of health condition studied**

Recurrent pregnancy loss

**ICD-10 code**

XV

**ICD-10 code description**

Pregnancy, childbirth and the puerperium

**Primary outcomes****1****Description**

Pregnancy loss

**Timepoint**

Before 20th week of gestation

**Method of measurement**

Sonography

## Secondary outcomes

### 1

#### Description

Clinical pregnancy rate

#### Timepoint

6th week of pregnancy

#### Method of measurement

Sonography

### 2

#### Description

Live birth rate

#### Timepoint

At the end of pregnancy period

#### Method of measurement

Delivery

### 3

#### Description

Twin pregnancy

#### Timepoint

6th week of gestation

#### Method of measurement

Sonography

### 4

#### Description

Newborn weight

#### Timepoint

After delivery

#### Method of measurement

Weighting

## Intervention groups

### 1

#### Description

Intervention group: A single dose of intrauterine infusion of allogeneic decidualized menstrual blood stem cells with final volume of 0.5 ml containing 1 million cells.

#### Category

Treatment - Other

### 2

#### Description

Control group: A single dose of intrauterine infusion of sterile phosphate buffer

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

#### Name of recruitment center

Avicenna Infertility Clinic

#### Full name of responsible person

Amir-Hassan Zarnani

#### Street address

No. 97, Beginning of Yakhchal St., Shariati Ave.  
Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1998887621

#### Phone

+98 21 23519

#### Email

info@avicennaclinic.ir

#### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iranian academic center for education culture and research

##### Full name of responsible person

Mohammad-Reza Sadeghi

##### Street address

Avicenna Research Institute, Opposite to Faculty of Computer, Shahid Beheshti University, Evin, Chamran Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

2122432020

##### Phone

+98 21 2243 2020

##### Email

info@avicenna.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iranian academic center for education culture and research

#### Proportion provided by this source

100

#### Public or private sector

Private

#### 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**

Iranian academic center for education culture and research

**Full name of responsible person**

Amir-Hassan Zarnani

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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**Fax****Email**

zarnania@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

Amirhossein Zarnani

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Immunology

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## Person responsible for updating data

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**Full name of responsible person**

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Professor

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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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Protocol and the results of primary and secondary consequences

**When the data will become available and for how long**

After patent registry

**To whom data/document is available**

Investigators of universities and research institutes

**Under which criteria data/document could be used**

Research use

**From where data/document is obtainable**

Avicenna Research Institute, Amir-Hassan Zarnani

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

Formal written request to Avicenna Research Institute Chancellor

**Comments**

