

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Assessment of safety and effectiveness of in utero infusion of menstrual blood stem cells in treatment of recurrent implantation failure: A double-blind phase 1 and 2 clinical trial

#### Protocol summary

##### Study aim

Assessment of safety and effectiveness of in utero infusion of menstrual blood stem cells in treatment of recurrent implantation failure

##### Design

A randomized, double-blinded, sham controlled phase 1&2 clinical trial with a parallel group design of 20 patients followed for one year

##### Settings and conduct

About 20% of couples suffer from infertility. In this clinical trial, which is conducted in Avicenna Infertility Clinic, the potential effects of in utero infusion of decidualized menstrual blood-stromal/stem cells in treatment of infertility will be assessed. 40 infertile women will randomly be divided into two groups of intervention and controls. 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 implantation failure are recruited. Women with past history of pregnancy are not recruited.

##### Intervention groups

Forty women with unexplained recurrent implantation failure are randomly divided into two groups of 20. Women in experimental group will receive in utero infusion of decidualized menstrual blood-derived stromal/stem cells, while in control women sterile PBS buffer will be infused.

##### Main outcome variables

Side effects of in utero infusion of decidualized menstrual blood-derived stromal/stem cells  
Frequency 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: **IRCT20210513051280N1**

Registration date: **2021-05-19, 1400/02/29**

Registration timing: **prospective**

Last update: **2021-05-19, 1400/02/29**

Update count: **0**

##### Registration date

2021-05-19, 1400/02/29

##### 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 in utero infusion of menstrual blood stem cells in treatment of recurrent implantation failure: A double-blind phase 1 and 2 clinical trial

## Public title

Treatment of infertility with endometrial stem cells

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Women with recurrent implantation failure (Three unsuccessful embryo transfer cycles with transfer of at least one blast stage or one cleavage stage A in each cycle) No history of previous pregnancy FSH level of less than 10 mIU/mL Negative results for HIV, HBS Ag, HCV and VDRL

### Exclusion criteria:

Hydrosalpinx Stage 3 or 4 endometriosis Asherman's syndrome Endometrial organic disease Chromosomal abnormalities in parents Spermogram abnormalities (DFI more than 30 and Normal sperm morphology less than 2% PCO with metabolic syndrome Anti-phospholipid antibodies Autoimmune diseases including rheumatoid arthritis, thyroid autoimmunity, lupus History of cancer, chemotherapy or radiotherapy Thin endometrium History of immunosuppressive drug intake 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 using app.studyrandomizer software. The number of cases allocated to each group will be same with ratio of 1:1.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

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

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ACECR Research Ethics Committee

##### Street address

Enghelab Ave, Opposite to the main door of Tehran University, Central office of ACECR

##### City

Tehran

##### Province

Tehran

##### Postal code

4364 - 14155

##### Approval date

2021-03-15, 1399/12/25

##### Ethics committee reference number

IR.ACECR.REC.1399.008

## Health conditions studied

### 1

#### Description of health condition studied

Recurrent implantation failure

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Implantation rate

#### Timepoint

2 weeks after embryo transfer

#### Method of measurement

Measurement of B-HCG

## Secondary outcomes

### 1

#### Description

Clinical pregnancy rate

#### Timepoint

6 weeks after embryo transfer

#### Method of measurement

Sonography

### 2

#### Description

Live birth rate

#### Timepoint

At the end of pregnancy period

#### Method of measurement

Parturition

### 3

#### Description

Twin pregnancy

#### Timepoint

6 weeks after embryo transfer

#### Method of measurement

Sonography

### 4

#### Description

Newborn weight

#### Timepoint

After delivery

#### Method of measurement

Weighting

## Intervention groups

### 1

#### Description

Intervention group: intervention type: A single dose of in utero infusion of allogeneic in vitro decidualized menstrual blood stem cells with final volume of 0.5 ml containing 1 million cells.

#### Category

Treatment - Other

### 2

#### Description

Control group: intervention type: A single dose of in utero 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, Avicenna Infertility Clinic at the corner of the Yakhchal street Shariati st. Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1998887621

##### Phone

+98 21 23519

##### Email

info@avicennaclinic.ir

## 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

Evin, Shahid Beheshti University

##### City

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##### Province

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##### Postal code

2122432020

##### Phone

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##### 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

##### Street address

Evin, Shahid Beheshti University

##### City

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##### Province

Tehran

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zarnania@gmail.com

## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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Professor  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### 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**

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**Other areas of specialty/work**  
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**Email**  
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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

Academic and research institute investigators

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

Research use only

### 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 from ARI chancellor

### Comments