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
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No. 97, Beginning of Yakhchal St., Shariati Ave.
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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
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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
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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Avicenna Research Institute, Opposite to Faculty of Computer, Shahid Beheshti University, Evin, Chamran Highway, Tehran

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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