Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of safety and effectiveness of in utero infusion of menstrual blood stem cells in treatment of recurrent implantation failue: 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 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 tow 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)
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+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 failue: 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 cased allocated to each group will be same with ration 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
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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
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2122432020
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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
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Person responsible for updating data

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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