Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation and comparison of the safety and effectiveness of intra utrine injection of autologous menstrual blood-derived stem cells (MenSCs) and PRP in unfertilized women with thin unfunctional endometrium

Protocol summary

Study aim
Increase of endometrium and fertilization in patients with thin endometrium using menstrual blood stem cells

Design
Clinical trial including a control group, two-arm parallel-group, randomized trial

Settings and conduct
The entire population will be selected according to the inclusion and exclusion criteria and all patients must sign the informed consent. The subjects will be randomly divided into intervention and control groups. Menstrual blood will be collected from the patients of the intervention group at days 1 or 2 of their menstruation cycle using menstrual cups. Stem cells will be isolated from collected menstrual blood and cultured in vitro. Cultured cells will be evaluated for phenotyping and non-contamination. Autologous cells will be administered to the endometrium in the Avicenna Infertility Clinic. Whole blood will be collected from the control group and PRP will be injected into their endometrium.

Participants/Inclusion and exclusion criteria
married females, history of infertility, no responding to routine treatment, endometrium thickness bellow 7 mm on ovulation time, having at least 2 high-quality embryos in freeze cycle, endometrium tissue pattern of 3 and 4 based on Appelbaum classification exclusion criteria; thyroid dysfunction, Immunosystem diseases, history of cancer, chemotherapy, and radiotherapy, hepatitis C, B, and HIV infection, endometriosis, diabetes, liver and electrolyte disorders

Intervention groups
Intervention group: are treated by autologous stem cell infusion Control group: are treated by injection of PRP into their endometrium

Main outcome variables
Endometrium thickness, uterine arterial blood flow, presence of blood supply in zone 3 of the endometrium, improvement of endometrium patterns, spontaneous pregnancy, clinical pregnancy, Implantation rate, live birth rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180619040147N3**
Registration date: **2020-05-19, 1399/02/30**
Registration timing: **prospective**

Last update: **2020-05-19, 1399/02/30**
Update count: **0**

Registration date
2020-05-19, 1399/02/30

Registrant information

Name
Maryam Darzi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2021-09-23, 1400/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation and comparison of the safety and effectiveness of intra utrine injection of autologous menstrual blood-derived stem cells (MenSCs) and PRP in unfertilized women with thin unfunctional endometrium

Public title
Evaluation and comparison of the safety and effectiveness of Intra uterine injection of autologous menstrual blood-derived stem cells (MenSCs) and PRP in unfertilized women with thin unfunctional endometrium
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
married women under 7 mm thickness of endometrium showing 3-4 Appelbaum classification of endometrium tissue pattern minimum or no blood supply of zone 3 of endometrium score 1-0 of arterial blood flow into endometrium intrauterine adhesions a history of no responding to routine treatment for this issue having at least 2 high quality embryos in freeze cycle ages between 25-40
Exclusion criteria:
Thyroid disfunction Immune disorders history of cancer, chemotherapy and radiotherapy hepatitis B, C and HIV infections severe endometriosis diabetes Dysfunction of electrolyte or liver tests
Age
From **25 years** old to **40 years** old
Gender
Female

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization: In order to randomly assign 36 subjects in the treatment group or control group, 6 blocks including 6 subjects each will be defined using "https://app.studyrandomizer.com". Treatment group and control group will be identified by codes A and B, respectively. In each block, the number of treatment groups and control groups is equal and the situation of each block with other blocks is different.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not 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
1270, Secretariat of the Ethics Committee of ACECR,Deputy Director of Research and Technology, Headquarters of ACECR, Opposite the main door of Tehran University, Enghelab Street, Tehran
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tehran
Province
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Postal code
1936773493
Approval date
2020-02-23, 1398/12/04
Ethics committee reference number
IR.ACECR.REC.1399.001

Health conditions studied

1

Description of health condition studied
thin endometrium
ICD-10 code
R93.4
ICD-10 code description
Abnormal findings on diagnostic imaging of urinary organs

Primary outcomes

1

Description
endometrium thickness
Timepoint
1, 2 and 3rd month after injection
Method of measurement
Vaginal sonography

2

Description
uterine arterial blood flow
Timepoint
1, 2 and 3rd month after injection
Method of measurement
Vaginal sonography

3

Description
blood flow precence into zone 3 of the endometrium
Timepoint
1, 2 and 3rd month after injection
Method of measurement
vaginal sonography

4

Description
endomtrial tissue pattern
Timepoint
1, 2 and 3rd month after injection
Method of measurement
vaginal sonography

Secondary outcomes

1

Description
Implantation rate
Timepoint
in new intra-cytoplasmic sperm injection cycle after intervention
Method of measurement
vaginal sonography

2

Description
Clinical pregnancy
Timepoint
6-8 weeks after last menstrual period
Method of measurement
Vaginal sonography

3

Description
live birth
Timepoint
9 months after pregnancy
Method of measurement
delivery report based on gynecologist comment

Intervention groups

1

Description
Intervention group: includes 18 patients with thin endometrium that will be treated by once injection of autologous menstrual blood stem cells. After cells isolation, culture, and qualification in GMP grade- clean room of STERCO (Tehran, Iran), a suspension with a density of 10 million cells will be intravaginally injected by vaginal ultrasonography into the endometrium of patients after receiving general anesthesia
Category
Treatment - Other

2

Description
Control group: includes 18 patients with thin endometrium that will not receive any stem cells and they will only receive PRP into the endometrium under general anesthesia and their biochemical parameters, sonographic and embryologic data will be compared with intervention group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Avicenna Infertility Clinic
Full name of responsible person
Somaieh Kazemnejad
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No 97, Beginning of Yakhchal Street, Shariati Ave.
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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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Avicenna Research Institute, Shahid Beheshti University, Shahid Chamran Highway, Tehran, Iran
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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
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
Iranian academic center for education culture and research
Full name of responsible person
Somaieh Kazemnejad
Position
Associate Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable