Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of intra-uterine PRP injection on endometrial thickness and pregnancy result in women with recurrent implantation failure or thin endometrium under and over 35 years old undergoing freeze-thawed embryo transfer

Protocol summary

Study aim

Comparison of the effect of intra-uterine PRP injection on endometrial thickness and pregnancy result in women with recurrent implantation failure or thin endometrium under and over 35 years old undergoing freeze-thawed embryo transfer

Design

Phase 3 clinical trial with a control group will be conducted in parallel groups on 62 patients. Randomization of the samples will be done with a simple randomization method according to the generated list. The list of random numbers will be generated by a statistical consultant using Random Allocation1 software. 31 patients will be in the intervention group and 31 patients will be in the control group.

Settings and conduct

The clinical trial will be conducted in Semnan Amiralmomenin hospital. The study and control cases will be selected among patients referring to the infertility clinic who are candidates for freeze-thawed embryo transfer who suffer from recurrent implantation failure or thin endometrium despite of hormone replacement. In intervention group PRP will be done. In control group PRP will not be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women under 40 years old with recurrent implantation failure or thin endometrium who are candidate of freeze-thawed embryo transfer

Intervention groups

Both groups will be selected from infertile women candidate for freeze-thawed embryo transfer who suffer from recurrent implantation failure or thin endometrium despite of hormone replacement. In intervention group PRP will be done. In control group PRP will not be done.

Main outcome variables

Clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231119060109N1**
Registration date: **2023-12-05, 1402/09/14**
Registration timing: **prospective**

Last update: **2023-12-05, 1402/09/14**
Update count: **0**

Registration date

2023-12-05, 1402/09/14

Registrant information

Name

Sahereh Arabian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3344 1022

Email address

s.arabian@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-06-20, 1403/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of intra-uterine PRP injection on endometrial thickness and pregnancy result in women with recurrent implantation failure or thin endometrium under and over 35 years old undergoing freeze-thawed embryo transfer

Public title

Effect of intra-uterine PRP injection on endometrial thickness and pregnancy result in women with recurrent implantation failure or thin endometrium under and over 35 years old undergoing freeze-thawed embryo transfer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with recurrent implantation failure undergoing freeze-thawed embryo transfer Women with endometrial thickness of under 7mm on 13th day of hormone replacement cycle of freeze-thawed embryo transfer Women under 40 years old

Exclusion criteria:

Age over 40 years

Age

To **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization list of samples in groups will be generated using Random Allocation1 software. Then, according to the order of patient's referral and taking into account the criteria for entering the study, according to the patient's entry number from the list, the study group is announced to the researcher by the statistical consultant, and on each sample according to the study group , the intervention is done or they are placed in the control group

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

Ethics committee of Semnan University of Medical Sciences

Street address

Basij Blvd., Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2023-10-30, 1402/08/08

Ethics committee reference number

IR.SEMUMS.REC.1402.171

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

4 weeks after embryo transfer

Method of measurement

Observation of fetal heart activity by transvaginal ultrasonography

Secondary outcomes

1

Description

Chemical pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

Through blood sample for Beta Hcg

Intervention groups

1

Description

Intervention group: infertile women candidate for freeze-

thawed embryo transfer who suffer from recurrent implantation failure or thin endometrium despite of hormone replacement. In intervention group PRP will be done.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Nahid Azad

Street address

Mostafa Khomeini Blvd., Imam Hossein .,Semnan

City

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Semnan

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3519734731

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Email

amir.hospital@semums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Majid Mirmohammadkhani

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Semnan University of Medical Sciences, Basij Blvd, Semnan

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majidmir@semums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan University of Medical Sciences

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

Semnan University of Medical Sciences

Full name of responsible person

Nahid Azad

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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Position

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Person responsible for updating data

Contact

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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All participants data sets are to be shared.

When the data will become available and for how long
2 months after publication of results.

To whom data/document is available
Researchers of academic centers

Under which criteria data/document could be used
To evaluate the accuracy of data and to use them to complete other researches

From where data/document is obtainable
Submit your request by sending an email.

What processes are involved for a request to access data/document
By sending an e-mail, by reviewing the request and providing documentation and the reason for using the data, it will be provided within a week.

Comments