

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of intrauterine infusion of platelet-rich plasma and number of infusion on increasing the thickness of endometrium and pregnancy rate in patients with thin endometrium.

Protocol summary

Study aim

The effect of intrauterine infusion of platelet-rich plasma and number of infusion on increasing the thickness of endometrium and pregnancy rate in patients with thin endometrium.

Design

Randomized, not blinded, sham controlled clinical trial with a parallel group design of 20 patients, enrolled between January 2019 and July 2019, and followed for 20 weeks.

Settings and conduct

Twenty infertile women with thin endometrium on day 10 of freeze embryo transfer cycles who attending in infertility ward of Imam Khomeini Hospital, divided in two groups according to randomized number table, that once or twice platelet- rich plasma infusion on day 11 and 13 cycles. Changes in the ET, and pregnancy rate compared between the groups. Patients are aware and satisfied of the intervention, but the physician has no information about kind of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged between 20-40 years: BMI Between 20-30 kg/m²: Freez embryo transfer: Prior failed embryo transfer cycle due to thin endometrium: endometrial line below 7 on day 10 of cycle Exclusion criteria: Abnormal uterine form conture on hystrosalpingography or hysteroscopy: Hematologic disease: Hormonal disorder

Intervention groups

Intervention group 1: Intrauterine infusion of 0.5 CC of autologus platelet-rich plasma (has 4-6 times platelet concentration rather than peripheral blood by IUI catheter(Takvin company, Iran) on day 11 of freeze embryo transfer cycle. Intervention group 2: Intrauterine infusion of 0.5 CC of autologus platelet-rich plasma (has 4-6 times platelet concentration rather than peripheral blood by IUI catheter(Takvin company, Iran) on day 13 of

freeze embryo transfer cycle. Control group: Transfer of three Freeze embryos by chateter (Cook, USA) under ultrasonographic guidance.

Main outcome variables

Increase in endometrial thickness rate: Clinical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160815029374N5**

Registration date: **2019-05-11, 1398/02/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-11, 1398/02/21**

Update count: **0**

Registration date

2019-05-11, 1398/02/21

Registrant information

Name

Marzieh Zamaniyan

Name of organization / entity

Mazandaran University of Medical Sciences, Sari, Iran.

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intrauterine infusion of platelet-rich plasma and number of infusion on increasing the thickness of endometrium and pregnancy rate in patients with thin endometrium.

Public title

PRP in infertility

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women aged between 20-40 years BMI Between 20-30 kg/m2 Freez embryo transfer Prior failed embryo transfer cycle due to thin endometrium endometrial line below 7 on day 10 of cycle without endometrial pathology on hystrosalpingography or hysteroscopy

Exclusion criteria:

Abnormal uterine form cnture on hystrosalpingography or hysteroscopy Hematologic disease Hormonal disorder

AgeFrom **20 years** old to **40 years** old**Gender**

Female

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **20****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization is done based on the random number table on the day of estrogen initiation in freeze embryo transfer cycle by one nurse. In fact, only the nurse knows which patient is under the one or two PRP infusion. Physicians do not know which patient is undergoing one or two PRP, but patients know about the intervention due to informed consent, therefore, it is not possible to concealed the patients in this 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 Mazandaran University of Medical Sciences

Street address

No. 5, third floor, Cancer ward, Imam Khomeini Hospital, Amir Mazandarani Ave, Diabetes Research Center.

City

Sari

Province

Mazandaran

Postal code

3313148166

Approval date

2019-02-07, 1397/11/18

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.1398.014

Health conditions studied**1****Description of health condition studied**

Diseases of the genitourinary system

ICD-10 code

N97; N98

ICD-10 code description

Female infertility; Complications associated with artificial fertilization

Primary outcomes**1****Description**

Increase in endometrial thickness rate

Timepoint

48 hours after intrauterine injections of platelet-rich plasma

Method of measurement

Ultrasound

2**Description**

Clinical pregnancy rate

Timepoint

Forth weeks after embryo transfer

Method of measurement

Ultrasound

Secondary outcomes**1****Description**

Miscarriage rates
Timepoint
Till twenty weeks after embryo transfer
Method of measurement
Questionnaire

2

Description
Chemical pregnancy rate
Timepoint
Two weeks after embryo transfer
Method of measurement
B-HCG Kit

3

Description
Implantation rate
Timepoint
Forth weeks after embryo transfer
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Intrauterine infusion of 0.5 CC of autologous platelet-rich plasma (has 4-6 times platelet concentration rather than peripheral blood by IUI catheter(Takvin company, Iran) on day 11 of freeze embryo transfer cycle.
Category
Treatment - Other

2

Description
Intervention group: Intrauterine infusion of 0.5 CC of autologous platelet-rich plasma (has 4-6 times platelet concentration rather than peripheral blood by IUI catheter(Takvin company, Iran) on day 13 of freeze embryo transfer cycle.
Category
Treatment - Other

3

Description
Control group: Transfer of three Freeze embryos by chateter (Cook, USA) under ultrasonographic guidance.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center

Imam Khomainsi Hospital
Full name of responsible person
Marzieh Zamaniyan
Street address
No. 1, Ground floor, Infertility ward, Imam Khomeini Hospital, Amir Mazandarani Ave,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Fereshteh Akrami
Street address
N0.2, Third floor, Department of Research and Technology, Teachers' Square
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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
Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Marzieh Zamaniyan

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

Marzieh Zamaniyan

Position

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Latest degree

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Person responsible for updating data

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Full name of responsible person

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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

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