

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Clinical trial of pregnancy outcome in women with thin endometrium after intrauterine infusion of autologous platelet rich plasma (PRP) in comparison with women with thin endometrium without intervention undergoing frozen thawed cycles

Protocol summary

Summary

Objective: This study compares pregnancy outcome in two groups of 33 infertile women between 18 to 42 years with thin endometrium after intrauterine infusion of autologous platelet rich plasma (PRP) and thin endometrium women without intervention undergoing frozen thawed cycles. Design: this is a randomized clinical trial phase 3 study which is conducted in Yazd research and clinical center for infertility. Setting and conduct: in 2nd day of cycle a basic trans vaginal sonography is performed for the women. For all the women who enter in frozen thawed cycles, estradiol tablet 2mg three times daily is initiated. In 13th day of cycle trans vaginal sonography is done for the patients again. Participants: those who have endometrial thickness below 7mm enter in the study. They are divided in 2 groups randomly with table of random numbers with computerized software. In control group estradiol is continued for another 3 days Intervention: in interventional group PRP is infused intrauterine with IUI (intra uterine insemination) catheter. Endometrial thickness is measured after 48 hours. If endometrial thickness doesn't reach 7mm or above, the second dose of PRP will infuse. After 48 hours the endometrial thickness is measured and for whom with endometrial thickness above 7mm vaginal suppository Progesterone 400 mg twice daily is prescribed for 3 days then embryos in cleavage state are transferred. Main outcome measures: chemical pregnancy is evaluated with checking Bhcg 2 weeks after embryo transfer and clinical pregnancy is proved with trans vaginal sonography and observation of fetal heart 2 to 3 weeks after positive pregnancy test

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090328950N2**

Registration date: **2017-01-10, 1395/10/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-10, 1395/10/21

Registrant information

Name

Nosrat Neghab

Name of organization / entity

Research and Clinical center for Infertility, Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 7085

Email address

nosratneghab@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of pregnancy outcome in women with thin endometrium after intrauterine infusion of autologous platelet rich plasma (PRP) in comparison with women with thin endometrium without intervention undergoing frozen thawed cycles

Public title

Evaluation of intrauterine infusion of autologous platelet rich plasma (PRP) on in vitro fertilization (IVF)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women undergoing frozen thawed cycles; endometrial thickness less than 7 mm in 13 th day of cycle; age between 18 to 42 Exclusion criteria: hematological and immunological disorders; hormonal disorders; chromosomal and genetic abnormalities; uterine abnormalities (congenital or acquired)

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomized with table of random numbers with computerized software

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

Bouali Avenue, Safayeh, Yazd, Iran

City

Yazd

Postal code

8916877391

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

IR.ssu.rsi.rec.1395.17

Health conditions studied

1

Description of health condition studied

female infertility

ICD-10 code

N97.9

ICD-10 code description

female infertility unspecified

Primary outcomes

1

Description

endometrial thickness

Timepoint

13th, 15th day of menstrual cycle and in some patients 17th day of cycle

Method of measurement

trans vaginal sonography

Secondary outcomes

1

Description

chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

serum pregnancy test

2

Description

clinical pregnancy

Timepoint

4 weeks after embryo transfer

Method of measurement

trans vaginal sonography

Intervention groups

1

Description

Intervention group: In 2nd day of cycle the patients undergo a basic trans vaginal sonography. For all the women who enter in frozen thawed cycles, estradiol tablet 2mg three times daily is initiated. In 13th day of cycle trans vaginal sonography is done for the patients again. Those who have endometrial thickness below 7mm enter in the study. PRP is infused intrauterine with

IUI (intra uterine insemination) catheter. Endometrial thickness is measured after 48 hours. If endometrial thickness doesn't reach 7mm or above, the second dose of PRP will infuse. After 48 hours the endometrial thickness is measured and for whom with endometrial thickness above 7mm vaginal suppository Progesterone400 mg twice daily is prescribed for 3 days then embryos in cleavage state are transferred.

Category

Treatment - Drugs

2

Description

Control group: In 2nd day of cycle the patients undergo a basic trans vaginal sonography. For all the women who enter in frozen thawed cycles, estradiol tablet 2mg three times daily is initiated. In 13th day of cycle trans vaginal sonography is done for the patients again. Those who have endometrial thickness below 7mm enter in the study. They are divided in 2 groups randomly. In control group estradiol is continued for another 3 days .When endometrial thickness reaches 7mm or above, vaginal suppository Progesterone400 mg twice daily is prescribed for 3 days then embryos in cleavage state are transferred .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd research and clinical center for infertility Shahid sadoughi university of medical sciences

Full name of responsible person

Dr Maryam Eftkhar

Street address

Bouali Avenue, Safayeh, Yazd, Iran

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Dr Ali Mohammad Abdoli

Street address

Bahonar square, Yazd, Iran

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences, Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd research and clinical center for infertility Shahid sadoughi university of medical sciences

Full name of responsible person

Dr Nosrat Neghab

Position

Obstetrician &Gynecologist fellowship of infertility and IVF(studying)

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Obstetrician&Gynecologist fellowship of infertility and IVF associated professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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sadoughi university of medical sciences

Full name of responsible person

Dr Nosrat Neghab

Position

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and IVF(studying)

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty