

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of Autologous Platelet-Rich Plasma (PRP) on ovarian function in patients with premature ovarian failure and poor ovarian reserve

Protocol summary

Study aim

Study the effect of Autologous Platelet-Rich Plasma (PRP) on ovarian function in patients with premature ovarian failure and poor ovarian reserve

Design

Clinical trial with 30 patient in two intervention group without control group and outcome assessment

Settings and conduct

Infertile women refer to reproductive science institute At first check level of E2, FSH, LH and AMH then injection of PRP into ovary under sedation and vaginal sonography (2-4 cc for both ovaries) two times with 90 days interval .Recheck level of E2, FSH, LH and AMH monthly for two consecutive months between the two PRP injections.

Follow up patients for possible spontaneous pregnancy

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with premature ovarian failure patient with poor ovarian reserve (AFC<5-7 and AMH<0.5-1.1 ng/ml; Exclusion criteria: IgA deficiency Ovarian failure secondary to sex chromosome abnormality Pelvic adhesion scndary to abdominal surgery Chronic pelvic pain

Intervention groups

Intervention in two groups of premature ovarian failure and poor ovarian reserve. At first check level of E2, FSH, LH and AMH then injection of PRP into ovary under sedation and vaginal sonography (2-4 cc for both ovaries) .Recheck level of E2, FSH, LH and AMH monthly for two consecutive months and then the second PRP injection 90 days after the first one.

Main outcome variables

FSH level, AMH level, LH level, Estradiol level

General information

Reason for update

As the number of both POF patients and poor responders who were referred to Yazd Infertility Center was more than the first estimation, and based on patients'

insistence for receiving the new treatment method of PRP injection, we aimed to increase the number of study cases. Due to the decline and elevation of hormones levels in comparison with the baseline measurements and also spontaneous pregnancy occurrence in the first month after the first PRP injection, the interval between the first and the second PRP injections was extended to 90 days. All patients were followed up for possible spontaneous pregnancy until live birth. Finally the duration of study including recruiting and follow up was extended.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180818040828N2**

Registration date: **2018-11-22, 1397/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-28, 1399/12/10**

Update count: **2**

Registration date

2018-11-22, 1397/09/01

Registrant information

Name

Lida Saeed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 8000

Email address

Isaeid@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-01, 1397/06/10

Expected recruitment end date

2020-03-01, 1398/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Autologous Platelet-Rich Plasma (PRP) on ovarian function in patients with premature ovarian failure and poor ovarian reserve

Public title

The effect of Autologous Platelet-Rich Plasma (PRP) on ovarian function

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with premature ovarian failure patient with poor ovarian reserve (AFC<5-7 and AMH<0.5-1.1 ng/ml)

Exclusion criteria:

IgA deficiency Ovarian failure secondary to sex chromosome abnormality Pelvic adhesion secondary to abdominal surgery Chronic pelvic pain

AgeFrom **20 years** old to **42 years** old**Gender**

Female

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **30****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

This study consider two different groups (POF and poor ovarian reserve) and we do one similar procedure (injection of PRP in ovary) for them and study two group separately

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of reproductive science institute-

Yazd Shahid Sadoughi University of Medical Science

Street address

Bouali Ave, Safaeih

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.SSU.RSI.REC.1397.004

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

Premature ovarian failure

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

2**Description of health condition studied**

Poor ovarian responders

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

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

FSH level

Timepoint

Some days before injection and 1, 2 months after injection

Method of measurement

Check in laboratory

2**Description**

AMH level

Timepoint

Some days before injection and 1, 2 months after injection

Method of measurement

Check in laboratory

3**Description**

Estradiol level

Timepoint

Some days before injection and 1, 2 months after

injection

Method of measurement

Check in laboratory

4

Description

LH level

Timepoint

Some days before injection and 1, 2 months after injection

Method of measurement

Check in laboratory

Secondary outcomes

1

Description

Chemical pregnancy

Timepoint

1 year after the first PRP injection

Method of measurement

Laboratory measurement of Beta hCG

2

Description

Clinical pregnancy

Timepoint

5 weeks after positive Beta hCG

Method of measurement

Observation of fetal heart rate in sonography

3

Description

Live birth

Timepoint

36 weeks after positive Beta hCG

Method of measurement

Delivery of live-born baby

Intervention groups

1

Description

First intervention group (premature ovarian failure): At first test serum AMH, estradiol (E2), FSH and LH a few days before intervention. In intervention day PRP process with Rooyagen kit. Approximately, 8.5 ml collect from each patient. Sample place in room-temperature centrifuge set to 1600*g for 10 minute. Finally 1.5-2 ml PRP with 4-5 fold concentration and 2000 lymphocyte is ready and for activation add calcium gluconate to it. PRP injection into ovaries under sedation and transvaginal sonography guidance is done (2-4 ml for both ovaries) and serum AMH, estradiol(E2), FSH and LH test every month is measured for two consecutive months. 90 days later the second PRP injection is done. 1-year follow up of patients for possible spontaneous pregnancy.

Category

Treatment - Drugs

2

Description

Second intervention group (poor ovarian response): At first test serum AMH, estradiol (E2), FSH and LH a few days before intervention. In intervention day PRP process with Rooyagen kit. Approximately, 8.5 ml collect from each patient. Sample place in room-temperature centrifuge set to 1600*g for 10 minute. Finally 1.5-2 ml PRP with 4-5 fold concentration and 2000 lymphocyte is ready and for activation add calcium gluconate to it. PRP injection into ovaries under sedation and transvaginal sonography guidance is done (2-4 ml for both ovaries) and serum AMH, estradiol(E2), FSH and LH test every month is measured for two consecutive months. 90 days later the second PRP injection is done. 1-year follow up of patients for possible spontaneous pregnancy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd reproductive science institute

Full name of responsible person

Dr. Abbas aflatoonian

Street address

Bouali Ave, Safaeih

City

Yazd

Province

Yazd

Postal code

8916877391

Phone

+98 35 3824 7085

Fax

+98 35 3824 7087

Email

abbas_aflatoonian@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Masoud Mirzaei

Street address

Bahonar Square, Yazd University of Medical Science

City

Yazd

Province

Yazd

Postal code
8915173160
Phone
+98 35 3724 0171
Email
Masoudmirzaei@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Dr.Lida Saeed
Position
Assistant professor, Infertility fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Bouali Ave, Safaeih
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
+98 35 3824 7087
Email
Isaeed6@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Abbas Aflatoonian
Position

Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Reproductive Science Institute, Bouali Ave, Safaeih
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
+98 35 3824 7087
Email
abbas_aflatoonian@ssu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr.Lida Saeed
Position
Assistant Professor, Infertility Fellowship
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Reproductive Science Institute, Booali Ave, Safaeih
City
Yazd
Province
Yazd
Postal code
8916877391
Phone
+98 35 3824 7085
Fax
+98 35 3824 7087
Email
Isaeed6@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the privacy of patients

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study protocol, statistical analysis map, clinical study report after article edition will be available

When the data will become available and for how long

After article edition

To whom data/document is available

Researchers that work in university

Under which criteria data/document could be used

In retrospective studies

From where data/document is obtainable

Yazd reproductive sciences institute

What processes are involved for a request to access data/document

Demand from Vice president of research, propound in Research council to infertility center and after acceptance refer to research expert and receive the data

Comments