Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 scondary 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)
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+98 34 3132 8000
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lsaeid@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 scondary to abdominal surgery Chronic pelvic pain
Age
From **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 Scince
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 labratory

2

Description
AMH level
Timepoint
Some days before injection and 1, 2 months after injection
Method of measurement
Check in labratory

3

Description
Estradiol level
Timepoint
Some days before injection and 1, 2 months after

injection

Method of measurement

Check in labratory

4

Description

LH level

Timepoint

Some days before injection and 1, 2 months after injection

Method of measurement

Check in labratory

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 ovareis under sedation and transvaginal sonography guidance is done (2-4 ml for both ovaries) and serum AMM, 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 regency.

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 ovareis under sedation and transvaginal sonography guidance is done (2-4 ml for both ovaries) and serum AMM, 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 regency.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd reproductive science institute

Full name of responsible person

Dr. Abbas aflatoonian

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Bouali Ave, Safaeih

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.Masoud Mirzaei

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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
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
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Person responsible for scientific inquiries

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Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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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 bw 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 reseaech, propound in Research council to infertility center and after acception refer to research expert and receive the data

Comments