Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of autologous platelet-rich plasma on ovarian frejuvenalization

Protocol summary

Study aim
Determination of the effect of platelet-rich plasma injection on ovarian rejuvenation in women with early ovarian failure

Design
In this randomized controlled clinical trial, 60 women between 18 and 40 with early ovarian failure will be randomly assigned to intervention and control groups if they meet the inclusion criteria. In the intervention group PRP is used in addition to standard treatment. The ultrasound-guided injection of a 5-cc puncture needle is injected from the solution under the capsule of each ovary. The control group received only standard treatment. In both groups, clinical and chemical pregnancy, mean serum FSH levels, mean diameter, follicle count and ovarian volume will be measured and compared at 0, 2, 6 and 12 months post-intervention.

Settings and conduct
Women with premature ovarian failure referred to Fatemieh Hospital in Hamadan will receive PRP injection in addition to standard treatment and the outcome of the intervention will be compared to the control group within one year.

Participants/Inclusion and exclusion criteria
women with early ovarian failure Inclusion criteria: Amenorrhea diagnosis, age 18 to 40 years, POF diagnosis in the last three years Exclusion criteria: Systemic disease, treated with anticancer drugs, use of contraceptives

Intervention groups
In sterile conditions prepared PRP will inject into the ovary by a gynecologist under ultrasound guide.

Main outcome variables
Return of pregnancy within one year

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151123025202N2**
Registration date: **2019-11-10, 1398/08/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-10, 1398/08/19**
Update count: **0**

Registration date
2019-11-10, 1398/08/19

Registrant information

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Name of organization / entity
Hamedan University of Medical Of Science

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of autologous platelet-rich plasma on ovarian frejuvenalization

Public title
Assmenat addition of autologous platelet-rich plasma in premature ovarian failur effect rejuvenalization

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with amenorrhea before the age of 40
Exclusion criteria:
Amenorrhea due to a specific illness
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose, we will use four random blocks. So we use 4 sheets of paper on 2 sheets of letter 1 meaning intervention and on 2 sheets of letter 2 means comparison. We mix the sheets together and place them in the drawer of the table each time the patient is randomly drawn out of one of the sheets and has one or two letters written on the sheet, respectively, one by one. Two groups of intervention or comparison will be assigned. It should be noted that the drawn tabs will not be returned to the drawer until all 4 tabs have been selected. Therefore, once the last tab has been pulled out, all the tabs will be returned to the drawer again. The procedure will continue for the next 4 patients until the desired sample size is reached
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 Hamedan University of medical science
Street address
Shahid Fahmide Ave
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Hamedan
Province
Hamadan
Postal code
6517838677
Approval date
2019-03-09, 1397/12/18
Ethics committee reference number
IR.UMSHA.REC.1397.963

Health conditions studied

1

Description of health condition studied
premature ovarian failur
ICD-10 code
E28.3
ICD-10 code description
Primary ovarian failure

Primary outcomes

1

Description
Treatment of infertility
Timepoint
At intervention time(Base), 2, 6 and 12 months after intervention
Method of measurement
Hormonal testing and ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to receiving routine medication 5 ml of PRP after adding calcium as an activator is injected into the ovary with sterile conditions.
Category
Treatment - Drugs

2

Description
Control group: Only receive routine treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Dr Mahnaz Yavangi
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Sponsors / Funding sources

1

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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
Hamedan 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
Hamedan University of Medical Sciences
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Person responsible for updating data

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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
I am waiting for the results of the study

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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
No - There is not 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