Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effect of intraovarian platelet rich plasma activated with calcium gluconate and growth factors injection on infertile women with poor ovarian response and assisted reproductive techniques (ART) outcomes

Protocol summary

Study aim
Investigating the effect of PRP activated with calcium gluconate and enriched with growth factors on the ovaries of women with poor ovarian response and evaluating the outcomes of assisted reproductive techniques.

Design
A clinical trial with three parallel groups, single-blind, non-randomized, Phase 1, conducted on 30 patients.

Settings and conduct
21 women diagnosed with poor ovarian response visited the infertility clinic at Arash Women's Hospital for infertility treatments and are currently candidates for egg donation were enrolled in the study based on the inclusion and exclusion criteria. They received injections of platelet-rich plasma activated with calcium gluconate and enriched with growth factors under sterile conditions. The injections were administered 5 cc per ovary within 10 days following the end of menstrual bleeding. Levels of FSH, LH, estradiol, and AMH, as well as the number of antral ovarian follicles, were assessed before the injections and monthly thereafter for three months. Subsequently, the patients underwent assisted reproductive treatments, and outcomes related to these treatments, as well as hormonal changes such as increases in AMH and decreases in FSH, and pregnancy outcomes, were evaluated. only the data analyst is blinded.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Individuals aged 20-42 years Diagnosed with poor ovarian response No fertility issues in the patient's husband Exclusion Criteria: Ovarian failure due to gonadal dysgenesis Immunoglobulin A deficiency History of major pelvic surgeries Cancer

Intervention groups
Group 1: Platelet-Rich Plasma (PRP) injection. Group 2: Platelet-Rich Plasma (PRP) injection activated with calcium gluconate. Group 3: Platelet-Rich Plasma (PRP) injection combined with growth factors.

Main outcome variables
Chemical pregnancy, Clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240815062771N3**
Registration date: **2025-02-24, 1403/12/06**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-24, 1403/12/06**
Update count: **0**

Registration date
2025-02-24, 1403/12/06

Registrant information

Name
shahrzad zhaeentan
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 4486 8791
Email address
zhaeentan.shahrzad@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-19, 1403/12/01

Expected recruitment end date
2025-10-23, 1404/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of intraovarian platelet rich plasma activated with calcium gluconate and growth factors injection on infertile women with poor ovarian response and assisted reproductive techniques (ART) outcomes

Public title
Injection of Plasma Rich in Growth Factor (PRGF) in infertile women with poor ovarian response
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 20-42 years Three or fewer oocytes retrieved in at least one previous ovarian stimulation cycle and an abnormal ovarian reserve test or an antral follicle count of less than five to seven or AMH <0.5–1.1 ng/mL No fertility problems in the patient's husband
Exclusion criteria:
Ovarian failure due to gonadal dysgenesis and chromosomal abnormalities Immunoglobulin A deficiency History of major pelvic floor surgery that has resulted in severe pelvic adhesions. Use of anticoagulants Use of psychotropic medications Presence of psychiatric disorders Cancer History of chronic pelvic pain
Age
From **20 years** old to **42 years** old
Gender
Female

Phase
1-2
Groups that have been masked

- Data analyser

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **3**
peripheral blood sample
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Considering that this therapeutic intervention is interventional, it is not possible to perform blinding for the patient and the treating physician. However, the responsible physician for assessing the outcomes and the analyzing physician are blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Research Institute of Oncology, Hematology, and Cell Therapy
Street address
North Kargar Street, Shariati Hospital
City
Tehran
Province
Tehran
Postal code
13135-14117
Approval date
2024-10-05, 1403/07/14
Ethics committee reference number
IR.TUMS.HORCSCT.REC.1403.063

Health conditions studied

1

Description of health condition studied
poor ovarian response
ICD-10 code
E28.8
ICD-10 code description
Other ovarian dysfunction

Primary outcomes

1

Description
Number of eggs retrieved during oocyte retrieval
Timepoint
After oocyte retrieval
Method of measurement
Embryologist report

Secondary outcomes

1

Description
Anti Mullerian Hormone (AMH) level
Timepoint
Before injection, 1 month after injection and 3 months after injection
Method of measurement
Measurement in blood plasma with ELISA kit

2

Description
Estradiol Hormone level
Timepoint
Before injection, 1 month after injection and 3 months after injection
Method of measurement
Measurement in blood plasma with ELISA kit

3

Description
Follicle-Stimulation Hormone (FSH) level
Timepoint
Before injection, 1 month after injection and 3 months after injection
Method of measurement
Measurement in blood plasma with ELISA kit

4

Description
Antral ovarian follicles count
Timepoint
Before injection, 1 month after injection and 3 months after injection
Method of measurement
Ultrasound

5

Description
Number of embryos
Timepoint
72 hours after oocyte retrieval
Method of measurement
Embryologist report

6

Description
Chemical pregnancy
Timepoint
14 days after embryo transfer
Method of measurement
Human chorionic gonadotropin (HCG) serum level

7

Description
Clinical pregnancy
Timepoint
5 weeks after embryo transfer
Method of measurement
Observation of the presence of at least one gestational sac within the uterine cavity by ultrasound

Intervention groups

1

Description
Intervention group: PRP extracted from the patient's own blood sample into ovarian cortex
Category
Treatment - Other

2

Description
Intervention group: Injection of activated platelet-rich plasma with calcium gluconate into the ovarian cortex
Category
Treatment - Other

3

Description
Intervention group: Injection of platelet-rich plasma enriched with growth factors into the ovarian cortex (PRGF)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Women's Hospital
Full name of responsible person
Mahshad Khodarahmian
Street address
Resalat Highway, after Shahid Bagheri Highway, Shahid Baghdarnia Street (North Rashid) - Corner of Alley 162 (Shahid Abdul Majid) - Atash Women's General Hospital
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3283
Fax
+98 21 7788 3196
Email
hosp_arash@tums.ac.ir
Web page address
https://arash.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahshad Khodarahmian
Street address
Resalat Highway, after Shahid Bagheri Highway,

Shahid Baghdarnia Street (North Rashid) - Corner of Alley 162 (Shahid Abdul Majid) - Arash Women's General Hospital

City
Tehran

Province
Tehran

Postal code
1653915981

Phone
+98 21 7788 3283

Email
ma.khodarahmian@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mahshad Khodarahmian

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Biology

Street address
Qods Street, Poursina Street, Faculty of Medicine, Department of Anatomical Sciences, Room 3

City
Tehran

Province
Tehran

Postal code
1417653761

Phone
+98 21 6649 2277

Email
ma.khodarahmian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mahshad Khodarahmian

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Biology

Street address
Qods Street, Poursina Street, Faculty of Medicine, Department of Anatomical Sciences, Room 3

City
Tehran

Province
Tehran

Postal code
1417653761

Phone
+98 21 6649 2277

Email
ma.khodarahmian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Shahrzad Zhaeentan

Position
P.h.D

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Biology

Street address
Pour sina street, school of medicine, department of anatomy

City
Tehran

Province
Tehran

Postal code
1653915981

Phone
+98 21 4486 8791

Fax

Email
zhaeentan.shahrzad@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The patients' personal information will be kept completely confidential and only the test results and outcomes will be published. All data obtained in the research will be published in a reputable and relevant scientific journal.

When the data will become available and for how long

April 2026

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The data from this study can be used as an adjuvant treatment in patients with poor ovarian response undergoing IVF/ICSI and will be made available only to researchers and therapists in the medical field.

From where data/document is obtainable

Mahshad Khodarahmian Email: ma_khodarahmian@gmail.com

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

By sending an email to the correspond author

Comments