

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of intraovarian platelet rich plasma and recombinant FSH injection on infertile women with poor ovarian response

Protocol summary

Study aim

Investigation of the effects of intraovarian platelet rich plasma and rFSH injection on infertile patients

Design

This non randomized clinical trial with case and control groups is conducted on 30 women with convenience sampling after consulting the patient and her partner. Each patient's response will be compared with the previous own IVF cycle. Care provider and analyser are blinded regarding groups.

Settings and conduct

Poor responder in IVF cycle at Yas Hospital that are candidates for egg donation, are included.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20-45 years old women with history of poor ovarian response in previous cycle. Exclusion criteria: Male infertility, Ovarian failure due to gonadal dysgenesis

Intervention groups

Intervention group: rFSH and platelet rich plasma is obtained from patients peripheral blood and injected in the ovaries by transvaginal ultrasonographic guidance under anesthesia at day of OPU. Control group: Oocyte puncture will be performed by ultrasonographic guidance under anesthesia at day of OPU and after three months ovarian function will be compared.

Main outcome variables

Three months after intervention, patients undergo IVF and the numbers of oocyte, chemical, clinical pregnancy outcome are followed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N33**

Registration date: **2023-09-16, 1402/06/25**

Registration timing: **prospective**

Last update: **2023-09-16, 1402/06/25**

Update count: **0**

Registration date

2023-09-16, 1402/06/25

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of intraovarian platelet rich plasma and recombinant FSH injection on infertile women with poor ovarian response

Public title

Effects of intraovarian PRP, rFSH injection in poor ovarian responder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Abnormal ovarian reserve test. Antral follicle count<5. At least one previous IVF cycle <3oocyte was retrieved.

Exclusion criteria:

Ovarian insufficiency due to gonadal dysgenesis and abnormality of chromosomes Male infertility

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Ethic committee of Tehran University of medical sciences

Street address

Deputy of Research, central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

159781597815

Approval date

2023-08-30, 1402/06/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.304

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

Female inf

ICD-10 code description

N97.8

Primary outcomes

1

Description

FSH,LH,AMH,Esteradiol levels

Timepoint

Before and three months after intervention

Method of measurement

Laboratory tests

2

Description

Chemical pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

Bhcg tests

3

Description

Number of MII oocyte

Timepoint

Three months after intervention

Method of measurement

Embryologist report

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

Four weeks after embryo transfer

Method of measurement

Heart beat activity in transvaginal sonogram

Intervention groups

1

Description

Intervention group:r FSH and platelet reach plasma that is prepared from patient's peripheral blood and injected in the ovarian tissue by transvaginal ultrasonographic guidance at the day of oocyte punctuer under anesthesia after three months, ovarian function will be compared with pervious cycle.

Category

Treatment - Drugs

2

Description

Control group: Under anesthesia and ultrasonographic guidance at the day of oocyte puncture will be performed and after three months, ovarian function will be compared with previous cycle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

YAS hospital

Full name of responsible person

Fatemeh Davari Tanha

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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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

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

Fatemeh Davari Tanha

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Undecided - It is not yet known if there will be 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

Outcome data

**When the data will become available and for how
long**

After publishing article

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Mention in references

From where data/document is obtainable

Request by email

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

Two weeks after request

Comments