# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 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 critria: 20-45 years old women with historyof poorovarianresponse 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 punctuer 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

**Country**
Iran (Islamic Republic of)

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+98 21 8831 3955

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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 dysgenesia and abnormality of chromosoms 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 pervious 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
**Street address**
Deputy of Research, sixth floor of central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd
**City**
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**Province**
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**Email**
afotouhi@tums.ac.ir
**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
**Street address**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Professor

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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**