

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effects of intraovarian platelet rich plasma injection on infertile women with poor ovarian response in Yas Hospital and evaluation of ovarian response to next IVF cycle

Protocol summary

Study aim

Investigation of the effects of intraovarian platelet rich plasma injection on infertile women with poor ovarian response

Design

This clinical trial is studied on 20 women with convenience sampling after consulting the patient and her partner. Each patient's response will be compared with the previous own IVF cycle.

Settings and conduct

This study is going to be conducted at Yas Hospital on the women who previously received conventional infertility treatments and now they are candidates for egg donation. The patient and the physician who does the intervention can not be blinded but the follow up and data analysis are blinded. At 14 th day of cycle under analgesia PRP is performed by transvaginal ultrasonography and needle of ovarian punctuer.

Participants/Inclusion and exclusion criteria

Inclusion critria: - 20-45 years old women -At least one previous IVF cycle with three or less ova and one of the followings: An abnormal ovarian reserve test Antral follicular count less than five follicles - Egg donation candidate Exclusion criteria: - Male infertility Ovarian failure due to gonadal dysgenesis or chromosomal abnormalities

Intervention groups

Platelet reach plasma is obtained from patients peripheral blood and injected in the ovaries by transvaginal ultrasonographic guidance under anesthesia.

Main outcome variables

FSH, LH, ESTRADIOL and anti-mullerian hormone (AMH) level, antral follicular count and menstruation pattern before PRP and monthly until three months after that are controlled; then 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: **IRCT20091012002576N19**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8831 3955

Email address

fdavaritanha@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of intraovarian platelet rich plasma injection on infertile women with poor ovarian response in Yas Hospital and evaluation of ovarian response to next IVF cycle

Public title
The effects of intraovarian platelet rich plasma injection on infertile women with poor ovarian response

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 25-40 years old Abnormal ovarian reserve test Antral follicle count<5 At least one previous IVF cycle <oocyte was retrieved
Exclusion criteria:
Ovarian insufficiency due to gonadal dysgenesis and abnormality of chromosoms Male infertility

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethic committee of Tehran University of Medical sciences

Street address

North Nejatollahi Avenue- Yas Hospital

City

Tehran

Province

Tehran
Postal code
15786
Approval date
2020-07-22, 1399/05/01
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.257

Health conditions studied

1

Description of health condition studied

Female infertility due to poor ovarian response, egg donation candidate

ICD-10 code

N97.8

ICD-10 code description

female infertility of other origin

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

After fetal transfer

Method of measurement

Ultrasound

Secondary outcomes

1

Description

Chemical pregnancy

Timepoint

Two weeks after fetal transfer

Method of measurement

Laboratory positive beta HCG test

2

Description

Gestational sac by transvaginal sonography

Timepoint

Three weeks after embryo transfer

Method of measurement

Transvaginal sonography

3

Description

Fetal heart activity by transvaginal sonography

Timepoint

Four weeks after embryo transfer

Method of measurement

Ultrasound

4

Description

FSH,LH,AMH,Esteradiol

Timepoint

Before and 3 months after intervention

Method of measurement

Laboratory tests

Intervention groups

1

Description

Intervention group: platelet rich plasma is prepared from patient's peripheral blood and injected in the ovarian tissue by transvaginal ultrasonographic guidance under anesthesia.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Yas Hospital

Full name of responsible person

فاطمه داوری تنها

Street address

Yas Hospital, North Ostad Nejatollahi St., Villa St., Karimkhan bridge

City

Tehran

Province

Tehran

Postal code

1597856511

Phone

+98 21 8894 8218

Email

fatedavtanha@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari-Tanha

Street address

North Nejatollahi Avenue- Yas Hospital

City

Tehran

Province

Tehran

Postal code

15978

Phone

+98 21 8880 0115

Email

fatedavtanha@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

معاونت پژوهشی دانشگاه علوم پزشکی تهران

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

North Nejatollahi Avenue-Yas Hospital

City

Tehran

Province

Tehran

Postal code

15978

Phone

+98 21 8880 0115

Email

fatedavtanha@gmail.com

Person responsible for scientific 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

North Nejatollahi Avenue-Yas Hospital

City

Tehran

Province

Tehran

Postal code

15978

Phone

+98 21 8880 0115

Email

fatedavtanha@gmail.com

Person responsible for updating data**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

North Nejatollahi Avenue- Yas Hospital

City

Tehran

Province

Tehran

Postal code

15978

Phone

+98 21 8880 0115

Email

fatedavtanha@gmail.com

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

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

Project report to Deputy of Research of TUMS, every researcher who needs data for research.

When the data will become available and for how long

Two years

To whom data/document is available

Deputy of Research of TUMS, every researcher who needs data for research.

Under which criteria data/document could be used

Final report and published the results, data is delivered to every researcher who needs it for research or systematic review .

From where data/document is obtainable

Miss Moamaei-Deputy of Research of TUMS, fifth floor, Central building of TUMS, Ghods ave.,
Tel:00982164431

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

Miss Moamaei-Deputy of Research of TUMS or send the request to fatedavtanha@gmail.com, responsible author, after 7 days I will respond

Comments