

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

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

Protocol summary

Study aim

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

Design

This non randomized clinical trial, phase 2-3, 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 as control.

Settings and conduct

This non randomized clinical trial with case & control group will be conducted on poor responder in IVF cycle in Yas hospital, women who are candidates for egg donation, are included. The care provider and analyser are blinded regarding groups. At OPU day PRP, Gh will be injected to the ovary & in control group only oocyte puncture will be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 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

Case group: Growth hormone and platelet rich plasma, which is obtained from 10 cc peripheral blood, injected in the ovaries, before extraction of needle, by transvaginal ultrasonographic guidance under anesthesia at day of OPU. Control group: previous cycle oocyte puncture was performed.

Main outcome variables

Numbers of oocyte, chemical, clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N32**

Registration date: **2023-09-05, 1402/06/14**

Registration timing: **prospective**

Last update: **2023-09-05, 1402/06/14**

Update count: **0**

Registration date

2023-09-05, 1402/06/14

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

fdavaritanha@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Intraovarian PRP & Gh in poor ovarian responder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20-40 years old with abnormal ovarian reserve test. Antral follicle count < 5. At least one previous IVF cycle < 3 oocyte 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: **60**

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

Ethics committee of Tehran University of medical sciences

Street address

Deputy of Research, sixth floor of 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.1402.305

Health conditions studied

1

Description of health condition studied

Female infertility of other origin

ICD-10 code

N97.8

ICD-10 code description

Female infertility of other origin

Primary outcomes

1

Description

Chemical pregnancy

Timepoint

Two weeks after fetal transfer

Method of measurement

Beta HCG test

2

Description

AMH

Timepoint

before and 3 months after intervention

Method of measurement

Measurements blood levels of AMH by Eliza method

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: Gh and platelet rich plasma that is prepared from patient's peripheral blood and injected in the ovarian tissue by transvaginal ultrasonographic guidance at the day of oocyte puncture under anesthesia after three months, ovarian function will be compared with previous cycle.

Category

Treatment - Surgery

2

Description

Control group: previous cycle of each patient which oocyte puncture was performed.

Category

Treatment - Surgery

Type of organization providing the funding
Academic

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

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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

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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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

No - There is not a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

IPD collected for the primary outcome measure only.

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

After presenting approved proposal, unidentified patients
data available for statically analysis.

From where data/document is obtainable

Dr.Davari,Fatedavtanha@gmail.com

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

Request by email

Comments