Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 punctuer will be performed.

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
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 punctuer 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

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Iran (Islamic Republic of)

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+98 21 8831 3955

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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 <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: **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
Ethic 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 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 - Surgery

2

Description
Control group: pervious cycle of each patient which oocyte punctuer was performed.
Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Yas hospital

Full name of responsible person
Fatemeh Davari Tanha

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North Nejatollahi Avenue, Karim khan Zand Bridge, Villa Street

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Fatedavtanha@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Akbar Fotouhi

Street address
Ghods Avenue, Keshavarz Blvd.

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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

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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