Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the IVF outcome in Methyl Testosterone consumers with placebo group in women with poor ovarian response referring to Yas infertility center

Protocol summary

Study aim
Comparison the IVF outcome in Methyl Testosterone consumers with placebo group in women with poor ovarian response referring to Yas Infertility center

Design
Double blind randomized placebo controlled clinical trial

Settings and conduct
This is a randomized clinical trial for poor responder patients at IVF cycle. Patients with< 3 oocyte retrieved in past IVF cycle or AMH<1.2 or Antral follicle count<5 are defined as poor res-ponder. 120 women according to the table of randomization number divided in both group; at case group patients received tab Methyltestosterone 25 mg/d for 2 months, control group receive placebo tablet at the same time . All the patients signed informed consent before participating in study. Then at the 2th day of menstruation both group evaluate by transvaginalsonogram, and 300U FSH start for 5 days, then GnRH antagonist start and the gonadotropin continue until mature follicle 18-20 mm appear at TVS,then Ovitrell 250 mg for triggering inject. After 36 hour oocyte spick up schedule. The number of oocytes ,embryos, transferred embryo, and chemical and clinical pregnancy will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 35-42 y/o; history of<3 oocyte retrieved in past IVF cycle; AFC<5; AMH<1.2. Exclusion criteria: history of ovarian surgery; systemic disease; abnormal profiles of the blood sugar, cholesterol or triglyceride; thyroid disorders; renal dysfunction; liver dysfunction.

Intervention groups
In case group patients use tablet methyl testosterone daily for two months before IVF cycle

Main outcome variables
Number of oocyte retrieved at OPU day; number of embryo at 3th day; B-hCG at 3th day

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091012002576N16**
Registration date: **2018-06-17, 1397/03/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-17, 1397/03/27**
Update count: **0**

Registration date
2018-06-17, 1397/03/27

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
2018-06-10, 1397/03/20

Expected recruitment end date
2018-10-22, 1397/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison the IVF outcome in Methyl Testosterone consumers with placebo group in women with poor ovarian response referring to Yas infertility center

Public title
Comparison the IVF outcome in Methyl Testosterone consumers with placebo group in women with poor ovarian response referring to Yas infertility center

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The number of oocytes punctured from them in previous cycles was less than or equal to 3 Antral follicle count less than 5 AMH less than 1.2

Exclusion criteria:
The history of ovarian surgery Systemic disease abnormal profiles of the blood sugar, cholesterol or triglyceride Thyroid disorders Renal dysfunction Liver Dysfunction

Age
From **35 years** old to **42 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Table of random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
According to the table of random numbers patients divide to two groups: in case group patients receive tablet methyl testosterone daily 2 months before starting IVF cycle, in control group patients receive placebo for two months, then both group start IVF cycle , oocytes are retrieved and counted, then at third day the embryos will be transferred to the uterus, the B-hCG results will be measured at 14th day after embryo transfer.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of the Tehran University of Medical Sciences

Street address
Yas hospital, North Ostadnejatollahi, Karimkhan Bridge, Villa street

City
Tehran

Province
Tehran

Postal code
1597856511

Approval date
2018-05-28, 1397/03/07

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.035

Health conditions studied

1

Description of health condition studied
Poor responder in IVF

ICD-10 code
N97

ICD-10 code description
Female infertility

Primary outcomes

1

Description
Number of oocyte retrieved

Timepoint
In the day of oocyte puncture

Method of measurement
Number of oocyte retrieved

Secondary outcomes

1

Description
Number of embryo

Timepoint
Day 3 after injection

Method of measurement
Number of embryo

Intervention groups

1

Description
Intervention group: sixty patients include in the case

group and use tablet methyletestesteron 25 mg, 1 daily, for 2 months before IVF cycle

Category
Treatment - Drugs

2

Description
Control group: Sixty patients in control group use placebo for 2 months before starting IVF cycle

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Yas women Hospital

Full name of responsible person
Fatemeh Davari Tanha

Street address
North Ostad Nejatollahi- Villa street, Karimkhan Bridge

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Tehran

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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
Miss Atefeh Ahmadi

Street address
Deputy research of TUMS; Fifth floor of Central building of Tehran University of Medical Sciences, Ghodse Avenue, Keshavarz Boulvard

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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
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact

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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

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

Data file anonymous

When the data will become available and for how long

After 3 years

To whom data/document is available

For University researchers

Under which criteria data/document could be used

For research projects

From where data/document is obtainable

Fatemeh Davari Tanha

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

After acceptance of research deputy of Tehran University of Medical sciences , data will be present at 3-6 months

Comments