

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 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)

Phone

+98 21 8831 3955

Email address

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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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+98 21 8880 0611

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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 Boulevard

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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

Name of organization / entity
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Other areas of specialty/work
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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

Fateme 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