# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## The effects of testosterone gel administration in the ovarian response to FSH in older women with poor response to traditional methods of assisted reproduction

## Protocol summary

**Summary**

In this study, 64 infertile women with inclusion criteria were selected and randomly divided into intervention and control groups.Participants divided into two groups of 32 people in two consecutive cycles (first cycle: Cycle Control CC, second cycle: treatment cycle TC) are examined.Hormones and sonographic evaluations are monitored.10,000 micro-units of HCG urine when at least three follicles have reached a diameter of 17 mm, both cycle and in both prescribed and administered for luteal phase progesterone support is 200 mg twice a day. Within 15 to 20 days by administration of a GnRH agonist to suppress pituitary and ovarian stimulation for IVF and ICSI is the second period, the rate of 1 mg daily testosterone gel 1% (10 mg) in the thigh and the outer surface The control group used a placebo gel.Time ultrasound within 2 to 4 days before the last administration of prescription gels and gel, and the FSH day to HCG day administration is prescribed.Hormones that are measured include E2, FSH, LH and progesterone are hormones by ECLIA done and measurement time of 2 to 4 days and on the last day of each cycle is administered gel.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201505197513N11**
Registration date: **2015-05-29, 1394/03/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2015-05-29, 1394/03/08

**Registrant information**

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Hatav Ghasemi Tehrani
**Name of organization / entity**
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**Recruitment status**

**Recruitment complete**

**Funding source**

esfahan University of medical scinces -Vice Chancellor for Research

**Expected recruitment start date**

2014-10-23, 1393/08/01

**Expected recruitment end date**

2015-02-19, 1393/11/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of testosterone gel administration in the ovarian response to FSH in older women with poor response to traditional methods of assisted reproduction

**Public title**

The effects of testosterone gel administration in ART

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1-aged between 30 and 42 years 2-

agreed to participate in the study 3- poor response to ovarian stimulation in IVF and ICSI methods previous (plasma estradiol level <1200 pg ml daily on HCG, the number of oocytes <5) 4- evidence of decreased ovarian reserve (which Drsvmyn day menstrual cycle, according to an abnormally low level of estradiol, inhibin B, and FSH defined) 5- no history of ovarian surgery, endometriosis, metabolic disorders and cancer Brest Exclusion criteria: 1- not referring patients to determine the level of hormones in ovarian reserves 2- lack of testosterone gel completely or irregular use it to continue the development of allergies or severe medical complications of drug use is prohibited. 3-Pregnancy

**Age**
From **30 years** old to **42 years** old

**Gender**
Female

**Phase**
4

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **64**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Isfahan University of Medical Sciences

**Street address**
Isfahan University of Medical Sciences- Hezar jarib Ave. - Isfahan

**City**
isfahan

**Postal code**

**Approval date**
2012-06-21, 1391/04/01

**Ethics committee reference number**
394067

## Health conditions studied

**1**

**Description of health condition studied**
infertility

**ICD-10 code**
N97.0

**ICD-10 code description**
Female infertility associated with anovulation

## Primary outcomes

**1**

**Description**
ovarian reserve hormones ( FSH-LH-Progestrone-E2)

**Timepoint**
end of each cycle

**Method of measurement**
laboratory assessment

**2**

**Description**
Antral follicles numbers

**Timepoint**
end of each cycle

**Method of measurement**
sonography

**3**

**Description**
Antral follicles size

**Timepoint**
end of each cycle

**Method of measurement**
sonography

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
1 mg daily of placebo gel (10 mg) on the external surface of the thigh in the control group

**Category**
Treatment - Drugs

**2**

**Description**
1 mg daily testosterone gel 1% (10 mg) on the external surface of the thigh in the intervention group

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

isfahan shahid beheshti hospital

**Full name of responsible person**

**Street address**

**City**

isfahan

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

research management

**Street address**

School of Medicine - Isfahan University of Medical Sciences - Hezar jarib Ave.

**City**

isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

medical science school

**Full name of responsible person**

atena khayambashi

**Position**

Obstetrics and Gynecology resident

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## Person responsible for scientific inquiries

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**Position**

resident

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*