

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

Name

Hatav Ghasemi Tehrani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 913 113 4081

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Recruitment status

Recruitment complete

Funding source

esfahan University of medical sciences -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 Breast 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

Other areas of specialty/work

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Name of organization / entity

Department of Obstetrics and Gynecology, School of Medicine, Isfahan University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical sciences

Full name of responsible person

atena khayambashi

Position

resident

Other areas of specialty/work

Street address

City

Postal code

Phone

00

Fax

Email

Web page address

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