# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Jul 2026

## The randomized single-blinded clinical trial comparing growth hormone effect versus placebo on Improving the outcome of pregnancy in infertile patients.

## Protocol summary

**Study aim**

Investigation the effect of GH injection on improving quality of follicle in poor ovarian responder.

**Design**

In this phase 3 three arms single- blinded trial, 105 infertile patients with poor ovarian response after signing inform consent assessing inclusion and exclusion criteria will recruit to study and randomly divided into three groups A, B &C. In intervention group A GH at the 8 cycle, in intervention group B GH in the early cycle and in intervention group C placebo injected until received 18 mm follicle, the oocyte quality will evaluated by embryologist after ova pick up .

**Settings and conduct**

The location of the study infertility ward in Dr Shariati Hospital. This is a single blind trial, and patients are not aware of the type of growth hormone or placebo.

**Participants/Inclusion and exclusion criteria**

Inclusioncriteria: Sign the informed consent form, Patients with poor ovarian response, (Having a maximum of 3 ovum after induction ovulation protocols,AFC less than 5, AMH less than 0.5 -1.1 ng/ml) Exclusion criteria: Women with FSH level more than 20 IU / L; women with diabetics melitus.

**Intervention groups**

In intervention group A continued with a Growth Hormone called Somatropine (2.5 mg) subcutaneously from the eighth day of the cycle, Growth Hormone injection in intervention group B from early cycle and In the intervention group C placebo (normal saline) is injected until reaching the follicle of more than 18 mm.

**Main outcome variables**

Main outcome measures include: The dose and frequency of injection of HMG, the number and quality of mature follicles, number and quality of eggs and the number of ovocytes obtained puncture, resulting embryo, the embryo transferring, clinical and laboratory fertility rate, abortion rate and live birth. rate. We expect that there is a significant difference in the control group between the investigation group.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20140818018842N14**
Registration date: **2018-08-11, 1397/05/20**
Registration timing: **retrospective**

Last update: **2018-08-11, 1397/05/20**
Update count: **0**

**Registration date**

2018-08-11, 1397/05/20

**Registrant information**

**Name**

Leyla Sharifi Aliabadi

**Name of organization / entity**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice president of research Tehran University of Medical Science (TUMS).

**Expected recruitment start date**

2016-04-20, 1395/02/01

**Expected recruitment end date**
2017-08-23, 1396/06/01
**Actual recruitment start date**
2016-04-20, 1395/02/01
**Actual recruitment end date**
2017-09-11, 1396/06/20
**Trial completion date**
empty

**Scientific title**
The randomized single-blinded clinical trial comparing growth hormone effect versus placebo on Improving the outcome of pregnancy in infertile patients.

**Public title**
“Effect of treatment with growth hormone in infertility”
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Sign the informed consent form Patients with poor ovarian response based on criteria provided by the Union embryology and infertility Europe 2011. Strong history of poor ovarian response (Having a maximum of three ovum after inducing ovulation protocols) Low score ovarian reserve (AFC less than 7, AMH less than 0.5-1.1 ng/ml)
**Exclusion criteria:**
Women with high levels of FSH (more than 20 IU/L) Women with a history of infertility due to known non poor ovarian resonce Women with diabetes (type I or II)
**Age**
From **20 years** old to **50 years** old
**Gender**
Female

**Phase**
3
**Groups that have been masked**

- Participant
- Data analyser

**Sample size**
Target sample size: **105**
Actual sample size reached: **105**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients are divided into 3 study groups by balanced block randomization. The list of randomized patients is made by a person not involved in the study and then the participants are randomly assigned into treatment groups.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
Patients recruited into trial after signing inform consent and assessing inclusion and exclusion criteria, randomly assigned to three groups A, B and C by a person not involved in the study, according to randomization patients will received drug (growth hormone or placebo), in the same package based on the protocol, the physician knows what treatment has been used but data analyzer is blinded.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Tehran University Medical Sciences
**Street address**
Ethics Committee of Tehran University of Medical Sciences, Keshavarz Boulevard, Tehran town.
**City**
Tehran
**Province**
Tehran
**Postal code**
1417653761
**Approval date**
2016-12-07, 1395/09/17
**Ethics committee reference number**
IR.TUMS.MEDICINE.REC.1395.1186

## Health conditions studied

**1**

**Description of health condition studied**
poor ovarian response
**ICD-10 code**
N97.0
**ICD-10 code description**
Female infertility associated with anovulation

## Primary outcomes

**1**

**Description**
The follicle number obtained in the ART cycle.
**Timepoint**
Before starting treatment, on day eighth of a cycle, 36 hours after injecting HCG
**Method of measurement**
Trans vaginal ultrasonography

## Secondary outcomes

**1**

**Description**

The number of metaphase II follicles achieved in the ART cycle.

**Timepoint**

According embryologist report at ovum puncture

**Method of measurement**

Count of meta-phase II follicles in embryologist ward by microscopic observation

**2**

**Description**

The number of quality embryos obtained from the ART cycle

**Timepoint**

Third and fifth day after fertilization in the laboratory

**Method of measurement**

Report embryologists based grading A, B, C.

**3**

**Description**

The number of positive pregnancy test

**Timepoint**

14 days after embryo transfer

**Method of measurement**

BHCG over than 40 IU

**4**

**Description**

Successful clinical pregnancy

**Timepoint**

6 to 8 weeks after embryo transfer

**Method of measurement**

Fetal Heart in Transvaginal ultrasonography

## Intervention groups

**1**

**Description**

Intervention group 1: received Gonadotropin (Gonal-f 300 to 450 IU/day, subcutaneously, based on age and follicular count) from the third day of the cycle plus GnRH antagonist (Cetrotide, 0.25mg/day, subcutaneously, after production of 14mm follicles) and growth hormone(Somatropin, 2.5mg/day, subcutaneously)from the eight day of the cycle for about 5 days.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group 2: received Gonadotropin (Gonal-f 300 to 450 IU/day, subcutaneously, based on age and follicular count) from the third day of the cycle plus GnRH antagonist (Cetrotide, 0.25mg/day, subcutaneously, after production of 14mm follicles) and growth hormone (Somatropin, 0.1mg/day, subcutaneously) from the third day of the previous cycle for about 20 days.

**Category**

Treatment - Drugs

**3**

**Description**

Intervention group 3: received Gonadotropin (Gonal-f 300 to 450 IU/day, subcutaneously, based on age and follicular count) from the third day of the cycle plus GnRH antagonist (Cetrotide, 0.25mg/day, subcutaneously, after production of 14mm follicles) and placebo (Normal saline 1ml/day, subcutaneously, uniformed to Somatropin) from the eight day of the cycle for about 5 days.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Infertility Ward, Dr shariati Hospital

**Full name of responsible person**

Atefe Samaei

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Infertility Ward, Dr shariati Hospital, North Kargar, Tehran Town.

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## Sponsors / Funding sources

**1**

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**Name of organization / entity**

Deputy of Research and Technology, Tehran University of Medical Sciences.

**Full name of responsible person**

Dr Mohammad ali Sahraeian

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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**
Deputy of Research and Technology, 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**
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Tehran University of Medical Sciences
**Full name of responsible person**
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**Position**
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## Person responsible for scientific inquiries

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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**
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**

All data is published after being unidentified.

**When the data will become available and for how long**

starting 12 months after publication.

**To whom data/document is available**

available for people working in academic institution and people working in businesses can also apply to receive it.

**Under which criteria data/document could be used**

The requirements for submitting a request for access to data and documentation include: - Certificate from university and research institutes - Field is a researcher related subject. - The focus of the people working in the industry on the subject matter.

**From where data/document is obtainable**

Access to information by sending an email to the following address may: asamaei@razi.tums.ac.ir

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

The receipt of the data after the submission of the documentation will be received up to a month after the submission of the request.

**Comments**