

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### The effect of androgen administration on IVF outcome in poor responders undergoing ovarian stimulation with microdose protocol

#### Protocol summary

##### Study aim

Study the effect of androgen administration on IVF outcome in poor responders undergoing ovarian stimulation with microdose protocol

##### Design

Two arm parallel group randomised trial

##### Settings and conduct

Infertile women refer to reproductive sciences institute

##### Participants/Inclusion and exclusion criteria

Poor responders, Severe endometriosis, Severe male factor, Uncontrolled endocrine disease

##### Intervention groups

Study the effect of adding androgen to ovarian stimulation with microdose protocol in study group and comparison with only microdose protocol in control group on IVF outcome in poor responders

##### Main outcome variables

Clinical pregnancy, Chemical pregnancy, Fetus number, Oocyte number, Dominant follicle

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180818040828N1**

Registration date: **2018-10-18, 1397/07/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-20, 1400/01/31**

Update count: **1**

##### Registration date

2018-10-18, 1397/07/26

##### Registrant information

##### Name

Lida Saeed

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 8000

##### Email address

Isaeid@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2018-11-22, 1397/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of androgen administration on IVF outcome in poor responders undergoing ovarian stimulation with microdose protocol

##### Public title

The effect of androgen administration on IVF outcome in poor responders

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patient with poor responder ovaries Age <45 years Age >18 years

##### Exclusion criteria:

Severe Endometriosis Severe Male Factor Uncontrolled Endocrine Disease

##### Age

From **18 years** old to **45 years** old

##### Gender

Female

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

At first the 60 qualified patients select and in order to refer from number 1 to 60 consider for them. Then with Random Allocation Software and random codes divide in two groups with 30 patients.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of reproductive sciences institute- Yazd Shahid Sadoughi University of Medical Scien

##### Street address

Bouali Ave, Safaeih

##### City

Yazd

##### Province

Yazd

##### Postal code

8916877391

#### Approval date

2018-05-20, 1397/02/30

#### Ethics committee reference number

IR.SSU.RSI.REC.1397.001

## Health conditions studied

### 1

#### Description of health condition studied

Patient with poor responder ovaries

#### ICD-10 code

N97

#### ICD-10 code description

Female infertility

## Primary outcomes

### 1

#### Description

Clinical pregnancy

#### Timepoint

5 Week after embryo transfer

#### Method of measurement

Vaginal Sonography to see fetus in gestational sac

## Secondary outcomes

### 1

#### Description

Chemical pregnancy

#### Timepoint

2 weeks after embryo transfer

#### Method of measurement

Check BHCG

### 2

#### Description

Fetus number

#### Timepoint

2-3 day after follicle aspiration

#### Method of measurement

Fetus in laboratory

### 3

#### Description

Oocyte number

#### Timepoint

In follicular aspiration day

#### Method of measurement

To see oocytes in laboratory

### 4

#### Description

The number of dominant follicle

#### Timepoint

In ovulation stimulation cycle

#### Method of measurement

Vaginal sonography

### 5

#### Description

Estradiol level in blood

#### Timepoint

To see 2-3 number of  $\geq 17$  mm follicle

#### Method of measurement

Check in laboratory

### 6

#### Description

Gonadotropin dosage

#### Timepoint

At the end of ovarian stimulation

#### **Method of measurement**

International Units

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: Since the 3rd day of menses will begin GnRH agonist buserelin acetate (Cinafact,cinagen,Iran) at a dose of 50 µg subcutaneously twice daily and menotropin(BSV,Germany ) 325 IU daily intramuscular.Follicular size with sonography and serum FSH, LH, P, and E2 level will be measured on cycle day 7 and then every 2-3 days one time. When serum FSH levels exceeded 20 IU/L on cycle day 7 or any time thereafter and follicular growth will considered to be slow or asynchronous (when one or two leading follicles were ≥4 mm larger than the rest of the cohort), gonadotropins will discontinue for 2-5 days. 40.5 mg of daily transdermal testosterone ( Androgel 1.62% , Abbvie) will begin from the day gonadotropin injections will interrupt until the day of the ovulation trigger. When at least two dominant follicles will reach to size of ≥17 mm, 10,000 IU hCG (Pregnyl, Netherlands) was administered subcutaneously for ovulation trigger. Thirty-six hours later, the oocytes were retrieved by means of ultrasound-guided transvaginal needle aspiration. Following egg retrieval, intracytoplasmic sperm injection/IVF will be done. The embryos will transferre at the cleavage stage 2-3 days later.

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Control group:Since the 2d day of menses GnRH agonist buserelin acetate (Cinafact,cinagen,Iran) at a dose of 50 µg subcutaneously twice daily and since the 4th day menotropin(BSV,Germany ) 325 IU daily intramuscular will begin.Follicular size with sonography will be measured on cycle day 9 and then every 2-3 days one time. In this group gonadotropin will not interrupt and will continue until trigger day. When at least two dominant follicles will reach to size of ≥17 mm,serum FSH,LH,P and E2 levels will be measured and10,000 IU hCG (Pregnyl, Netherlands) will administere subcutaneously for ovulation trigger. Thirty-six hours later, the oocytes were retrieved by means of ultrasound-guided transvaginal needle aspiration. Following egg retrieval, intracytoplasmic sperm injection/IVF will be done. The embryos will transferre at the cleavage stage 2-3 days later.

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Yazd reproductive sciences institute

###### **Full name of responsible person**

Dr.Abbas aflatoonian

###### **Street address**

Bouali Ave, Safaeih

###### **City**

Yazd

###### **Province**

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###### **Postal code**

8916877391

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###### **Email**

abbas\_aflatoonian@ssu.ac.ir

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Yazd University of Medical Sciences

###### **Full name of responsible person**

Dr.Masoud Mirzaei

###### **Street address**

Bahonar Square, Yazd University of Medical Scieincese

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###### **Email**

Masoudmirzaei@yahoo.com

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr.Lida Saeed

**Position**

Assistant professor, Infertility fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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lsaheed6@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr.Abbas Aflatoonian

**Position**

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**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr.Lida Saeed

**Position**

Assistant Professor, Infertility Fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Due to the privacy of patients

**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**

Study protocol,statistical analysis map,clinical study report after article edition will be available

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

After article edition

**To whom data/document is available**

Researchers that work in university

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

In retrospective studies

**From where data/document is obtainable**

Yazd reproductive sciences institute

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

Demand from Vice president of research,propound in Research council of infertility center and after acception refer to research expert and receive the data

**Comments**