

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effect of letrozole and dexamethasone with letrozole alone on ovarian response in infertile women

#### Protocol summary

##### Study aim

Comparison the effect of letrozole and dexamethasone with letrozole alone on ovarian response in infertile women

##### Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 120 infertile women.

##### Settings and conduct

This study will be conducted with the aim of comparison the effect of letrozole and dexamethasone with letrozole alone on ovarian response in 120 infertile women. After inclusion in the study, using block randomization with quadrilateral blocks method the patients will be assigned into two groups; letrozole plus dexamethasone group and letrozole-only group. In both groups 10 mg letrozole will be given from the days 3-5 of the cycle for 5 days and the dexamethasone will be given 0.5 mg orally from the day 4 to 15 of the cycle. Finally, in days 12-14 of the cycle the follicle diameter and endometrial thickness will be measured by trans-vaginal ultrasonography and will be compared together.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: all infertile women with polycystic ovarian syndrome; age 18-39 years Exclusion criteria: Using corticosteroid drugs; history of surgery on ovaries; endocrine abnormalities such as thyroid gland disorders

##### Intervention groups

Intervention group 1: Letrozole 10 mg from the days 3-5 of the cycle for 5 days plus 0.5 mg oral dexamethasone from the day 4 to 15 of the cycle Intervention group 2: Letrozole 10 mg from the days 3-5 of the cycle for 5 days

##### Main outcome variables

Follicle diameter Endometrial thickness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180318039129N1**

Registration date: **2018-03-27, 1397/01/07**

Registration timing: **prospective**

Last update: **2018-03-27, 1397/01/07**

Update count: **0**

##### Registration date

2018-03-27, 1397/01/07

##### Registrant information

###### Name

Fatemeh Afshar

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3329 5715

###### Email address

dr.f.afshar@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-04, 1397/01/15

##### Expected recruitment end date

2018-06-05, 1397/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of letrozole and dexamethasone with letrozole alone on ovarian response in infertile women

##### Public title

The effect of letrozole and dexamethasone on ovarian response

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

All infertile women with polycystic ovarian syndrome Age 18-39 years

#### **Exclusion criteria:**

Using corticosteroid drugs History of surgery on ovaries Endocrine abnormalities such as thyroid gland disorders

### **Age**

From **18 years** old to **39 years** old

### **Gender**

Female

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **120**

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

Randomized

### **Randomization description**

block randomization with quadrilateral blocks

### **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 Zahedan University of Medical Sciences

##### **Street address**

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9916789547

#### **Approval date**

2018-01-14, 1396/10/24

#### **Ethics committee reference number**

IR. ZAUMS. REC.1396.348

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Infertility

#### **ICD-10 code**

N97

#### **ICD-10 code description**

Female infertility

## **Primary outcomes**

### 1

#### **Description**

Follicle diameter

#### **Timepoint**

Between the days 12-14 of the cycle

#### **Method of measurement**

By trans-vaginal ultrasonography

### 2

#### **Description**

Endometrial thickness

#### **Timepoint**

Between the days 12-14 of the cycle

#### **Method of measurement**

By trans-vaginal ultrasonography

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Letrozole 10 mg form the days 3-5 of the cycle for 5 days plus 0.5 mg oral dexamethasone from the day 4 to 15 of the cycle

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 2: Letrozole 10 mg form the days 3-5 of the cycle for 5 days

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Ali Ebne Abi Taleb Hospital

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

Fatemeh Afshar  
**Street address**  
Khaliye Fars Blv, Zahedan  
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dr.f.afshar@zaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
Mohsen Taheri  
**Street address**  
Vice chancellor for research, Zahedan University of  
Medical Sciences, Zahedan  
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**Phone**  
+98 54 3329 5721  
**Email**  
Dr.Taheri@zaums.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
organization/entity?**  
Yes  
**Title of funding source**  
Zahedan 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**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Afshar

#### Position

Gynecology Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Zahedan University of Medical Sciences and Health  
Services campus, Khaliye Fars Blv, Doctor Hesabi Sq,  
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#### City

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#### Province

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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## Person responsible for updating data

#### Contact

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Zahedan University of Medical Sciences  
**Full name of responsible person**  
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**Latest degree**  
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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**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to  
make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable