Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 form 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 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 Intervention group 2: Letrozole 10 mg form 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
Khalije Fars Blv, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9916789547
Phone
+98 54 3329 5715
Email
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
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
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, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9916789547
Phone
+98 54 3329 5715
Email
dr.f.afshar@zaums.ac.ir

Person responsible for scientific 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, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9916789547
Phone
+98 54 3329 5715
Email
dr.f.afshar@zaums.ac.ir

Person responsible for updating data

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, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9916789547
Phone
+98 54 3329 5715
Email
dr.f.afshar@zaums.ac.ir

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