

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of letrozole alone with letrozole and N-Acetylcysteine for pregnancy rate in polycystic ovary syndrome patient who were undergone induction

Protocol summary

Study aim

Comparison of letrozole alone with letrozole and N-Acetylcysteine for pregnancy rate in polycystic ovary syndrome patient who were undergone induction of ovulation

Design

randomized clinical trial with two groups of control and intervention, random sampling without making blind

Settings and conduct

Molood clinic of Zahedan, a randomized clinical trial with sampling method on 162 patients

Participants/Inclusion and exclusion criteria

entry conditions: presence of two of oligo/involution criteria, clinical or laboratory based evidences of hyperandrogenism and polycystic ovaries in sonography, normal thyroid function and prolactin tests, normal fallopian tubes (by hystrosalpangography), normal semen analysis of the male partner: non entry conditions: thyroid and prolactin dysfunction, tubal abnormalities leading to infertility, medium to severe semen fluid abnormalities of sperm quantity, mobility and shape leading to infertility

Intervention groups

patients are divided randomly into 81 membered control (letrosol alone) and interventional (letrosol with n_acetyl cysteine) groups. the control group takes 5mg letrosol daily and interventional group takes 5mg letrosol with 1200mg NAC daily, both from third to seventh days of menstruation. 5 days after the last dose of letrosol; patients are examined on vaginal sonography due to measuring the endometrial thickness, quantity and diameter of matured follicles

Main outcome variables

the effect of Letrozole and the effect of both Letrozole and N-acetylcysteine in patients with polycystic ovarian disease

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180425039418N2**

Registration date: **2018-12-15, 1397/09/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-15, 1397/09/24**

Update count: **0**

Registration date

2018-12-15, 1397/09/24

Registrant information

Name

mohammad Ghena'at Pisheh Sanani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3343 1227

Email address

mohammad.ghenaat71@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of letrozole alone with letrozole and N-Acetylcysteine for pregnancy rate in polycystic ovary syndrome patient who were undergone induction

Public title

Comparison of letrozole alone with letrozole and N-Acetylcysteine for pregnancy rate in polycystic ovary syndrome patient who were undergone induction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

presence of two of oligo/involution criteria clinical or laboratory based evidences of hyperandrogenism and polycystic ovaries in sonography

Exclusion criteria:

thyroid and prolactin dysfunction tubal abnormalities leading to infertility medium to severe semen fluid abnormalities of sperm quantity, mobility and shape leading to infertility presence of cysts (larger than 6 cm), history of asthma and usage of drugs influencing on glucose metabolism within 3 month before study entrance

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **162**

Randomization (investigator's opinion)

Randomized

Randomization description

block: permutational, two groups with 81 members

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

Medical Sciences Campus, Doctor Hesabi Square,

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2018-07-01, 1397/04/10

Ethics committee reference number

IR.ZAUMS.REC.1397.167

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

2

Description of health condition studied

pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

the number of pregnancies

Timepoint

since the third day through seventh day after menstruation, 5 mg Letrozole was given to the group of control for 5 days and 5 mg Letrozole and 1200mg N-acetylcysteine were given to the group of intervention

Method of measurement

the structured checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: this randomized clinical trial will be done on patients with poly cystic ovarian disease who randomly will be selected as intervention and control group . the control group will have 5mg Letrozole at the third to seventh day after menstruation for 5 days

Category

Treatment - Drugs

2

Description

Intervention group 2: the intervention group will take 5mg Letrozole with 1200 mg N-acetylcysteine for 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Molood clinic

Full name of responsible person

Mohammad Hadi Abbasi

Street address

Ali-Ibne-Abitaleb hospital, KHalij Fars blv,Zahedan,Iran

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9816743111

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr.Seyyed Mohammad Hashemi

Street address

Ali-Ibne-Abitaleb hospital, KHalij Fars blv,Zahedan,Iran

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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

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

Sedigheh Mollashahi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available