

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of therapeutic effect of aromatase inhibitor with human gonadotropin in patients with clomiphene-resistant polycystic ovary syndrome

Protocol summary

Study aim

Comparison of ovulation induction with clomiphene and letrozole versus clomiphene and hormone Human gonadotropin in clomiphene-resistant patients with polycystic ovary syndrome

Design

Clinical trial with parallel groups of phase 2 on 120 patients

Settings and conduct

Patients will be sampled from the infertility center of Akbarabadi Hospital and the professors' office. The first group would be treated with a combination of clomiphene 100 mg from day 5 to 11 and letrozol 5 mg daily from day 5 to 9 of menstruation. On the 16th day of menstruation, they will be examined by transvaginal ultrasound. If there will be at least one follicle above 18 mm, HCG injection will be prescribed. The second group will be treated with a combination of clomiphene 100 mg daily from day 3 to 7 of menstruation and ampoules of human gonadotropin on days 6, 7 and 8 of menstruation. On the 18th day, they will be examined by transvaginal ultrasound and if there will be a follicle above 18 mm HCG, it will be prescribed for final induction.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women 18 to 40 years old with infertility of more than one year, without significant underlying disease, with one or two open fallopian tubes, normal spermogram. Exclusion Criteria: age group out of range, hypo or Hyperthyroidism. Hyperprolactinemia. Anatomical problems of the uterus and fallopian tubes.

Intervention groups

The two intervention groups included women with one-year infertility who are resistant to clomiphene, one group will receive clomiphene and human gonadotropin, and the second group will receive clomiphene and letrozole.

Main outcome variables

Endometrial thickness; Pregnancy rate; Number of follicles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211120053119N1**

Registration date: **2022-01-29, 1400/11/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-29, 1400/11/09**

Update count: **0**

Registration date

2022-01-29, 1400/11/09

Registrant information

Name

Maryam Dadkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3651 8189

Email address

mdadkhah27@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-06, 1400/09/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of therapeutic effect of aromatase inhibitor with human gonadotropin in patients with clomiphene-resistant polycystic ovary syndrome

Public title
Comparison of effects of an aromatase inhibitor with human gonadotropin in clomiphene-resistant polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with more than one year of infertility and clomiphene resistant polycystic ovary syndrome No significant underlying disease Has one or two open fallopian tubes Spouse normal spermogram
Exclusion criteria:
Age out of range Hypo or hyperthyroidism Hyperprolactinemia Anatomical problems of the uterus and fallopian tubes

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 Iran University of Medical Sciences
Street address
Tehran, Hemat Highway next to Milad Tower , 14535
City

Tehran
Province
Tehran
Postal code
1449614535
Approval date
2019-11-05, 1398/08/14
Ethics committee reference number
IR.IUMS.FMD.REC.1398.329

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome, infertility

ICD-10 code

سندرم تخمد

ICD-10 code description

سندرم تخمدان پلی کیستیک

Primary outcomes

1

Description

Number of follicles

Timepoint

On the 16th Day of the menstrual cycle

Method of measurement

Vaginal ultrasound machine

2

Description

Pregnancy rate

Timepoint

one month

Method of measurement

blood test

3

Description

Endometrial Thickness

Timepoint

On the 16th Day of the menstrual cycle

Method of measurement

Vaginal ultrasound machine

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in the first step, Patients with induce ovulation were treated with clomiphene (50mg tablet produced by Iran Hormone Company), 100 mg daily from

the 5th day of menstruation for 5 days, as well as on the 14th day of the ultrasound cycle. Even by prescribing clomiphene 150 mg for 7 days, patients still have not ovulated. In this study, these patients were considered clomiphene resistant patients and were divided into two equal groups of 60, each of them was placed in one of these two groups. The first group of patients was treated with a combination of clomiphene 100 mg from day 5 to 11 and letrozole 5 mg daily from day 5 to 9 of menstruation. On the 16th day of menstruation, transvaginal ultrasound was performed to check the number and size of follicles. Depending on the patient's condition, if there is at least one follicle above 18 mm, then 1 or 2 ampoules of HCG were prescribed for the final induction of ovulation.

Category

Treatment - Drugs

2

Description

Intervention group: The second group of patients was treated with a combination of clomiphene 100 mg daily from day 3 to 7 and ampoules of human gonadotropin hormone (ampoule 75 units produced by Karma company) on days 6, 7 and 8 of menstruation. The next doses were adjusted according to the patient's response. On day 18, transvaginal ultrasound was performed to check the size and number of follicles, and patient's condition, if there is at least one follicle above 18 mm, then 1 or 2 ampoules of HCG were prescribed for the final induction of ovulation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center of Akbarabadi Hospital and Dr. Ashrafi's office

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Vice Chancellor for Research, Iran University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

2

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Leila Irani

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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
Iran 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
Iran University of Medical Sciences
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Maryam Dadkhah
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
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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

Participants' data such as age, duration of infertility, type of infertility could be shared.

When the data will become available and for how long

Access starts 6 months after publishing results

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

To find out more about continuing the pregnancy

From where data/document is obtainable

Visit mdadkhah27@yahoo.com

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

After sending the request to the applicant and reviewing

the records, it will be sent via email about a month later.
Comments