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 11and letrzol 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: Women18 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

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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 pateints 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

Maryam Dadkhah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Full name of responsible person
Maryam Dadkhah

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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