

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Role of phyto-oestrogens (*Cimicifuga racimosa*) in combination with clomiphene citrate on ovulation induction in women with poly-cystic ovarian syndrome, A clinical Trial study

Protocol summary

Study aim

Development of Polycystic Ovarian syndrome Therapy methods

Design

This study is a prospective double-blind clinical trial performed on 100 women with polycystic ovary syndrome attending the Milad Hospital in Mashhad during 2016 to 2017. The randomization will be performed using sealed envelopes in which a green or blue card is placed inside.

Settings and conduct

This study is a double-blind which researcher and patient are unaware of the type of intervention. Participants will be women with polycystic ovarian syndrome

Participants/Inclusion and exclusion criteria

women with polycystic ovarian syndrome

Intervention groups

The intervention group: cimicifuga racimosa and clomiphene(20 mg) From the second day of the menstrual cycle for 10 days. Control group: Clomiphene citrate (50 mg) twice a day from the second day of the menstrual cycle for 5 days. It should be repeated three cycles.

Main outcome variables

Endometrium thickness, plasma estradiol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020264N2**

Registration date: **2018-01-04, 1396/10/14**

Registration timing: **retrospective**

Last update: **2018-01-04, 1396/10/14**

Update count: **0**

Registration date

2018-01-04, 1396/10/14

Registrant information

Name

Seyedeh Azam Pourhoseini

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 3847 1446

Email address

pourhoseinia@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of the Faculty of Medical Sciences, Mashhad

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of phyto-oestrogens (*Cimicifuga racimosa*) in combination with clomiphene citrate on ovulation induction in women with poly-cystic ovarian syndrome, A clinical Trial study

Public title

Role of phyto-oestrogens (*Cimicifuga racimosa*) in combination with clomiphene citrate on ovulation

induction in women with polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with polycystic ovarian syndrome Primary and secondary infertility Normal hysterosalpingography Normal Spermogram in patients' spouses Age below 38 years

Exclusion criteria:

History of cardiovascular disease History of liver disease History Ovarian masses

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

2

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization is done using closed envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study in which the researcher and the person who will analyze the data won't be aware of the type of drug.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical sciences

Street address

Mashhad University of Medical Sciences; International Offic Administration Center(Qoreishi Building) ; Daneshgah St.

City

Mashhad

Province

Fars

Postal code

13944-91388

Approval date

2014-07-23, 1393/05/01

Ethics committee reference number

931151

Health conditions studied

1

Description of health condition studied

polycystic ovarian syndrom

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

plasma estradiol

Timepoint

12 days after intervention

Method of measurement

sonography

Secondary outcomes

1

Description

endometrial thickness

Timepoint

12 days after intervention

Method of measurement

sonography

Intervention groups

1

Description

Intervention group: 20 mg Cimicifuga racimosa twice a day for 10 days with clomiphene citrate 50 mg twice a day for 5 days. The regimen will be started from the second day of the menstrual cycle and will be prescribed for three consecutive cycles.

Category

Treatment - Drugs

2

Description

Control group: clomiphene citrate 50 mg twice a day for 5 days. The regimen will be started from the second day of the menstrual cycle and will be prescribed for three consecutive cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Infertility Center

Full name of responsible person

Maliheh Amirian

Street address

Montserieh Infertility Therapy Research Center, next to Sina Hospital, East Razi Street

City

Mashhad

Province

Fars

Postal code

9135913556

Phone

+98 51 3802 2608

Email

pourhoseinia@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahyar Mirheidari

Street address

Mashhad University of Medical Sciences; International Office Administration Center (Qoreishi Building) ; Daneshgah St., Mashhad. Mashhad

City

Mashhad

Province

Fars

Postal code

9138813944

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name

گرانت پژوهشی

Grant code / Reference number

931151

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Mahmoodo Nia

Position

Resident of Obstetrics and Gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Imam Reza (AS) Hospital, Taghiabad Square

City

Mashhad

Province

Fars

Postal code

9138813944

Phone

+98 51 3802 2608

Fax**Email**

mahmodynia@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Seyedeh Azam Pourhoseini

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Imam Reza (AS) Hospital, Taghiabad Square

City

Mashhad

Province

Fars

Postal code

7449389918

Phone

+98 51 3802 2608

Fax**Email**

pourhoseinia@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyedeh Azam Pourhoseini

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Department of Obstetrics and Gynecology, Imam Reza (AS) Hospital, Taghiabad Square

City

Mashhad

Province

Fars

Postal code

7449389918

Phone

+98 51 3802 2608

Fax

Email

pourhoseinia@mums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Proposal

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

The researchers of Univerities

Under which criteria data/document could be used

Method and conclusion

From where data/document is obtainable

sent email to author

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

email: pourhoseinia@mums.ac.ir

Comments