

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Investigation of the effect of chamomile on ovulation induction and hormonal and clinical parameters in patients with polycystic ovary syndrome

Protocol summary

Study aim

Comparison of the effect of chamomile and placebo on ovulation induction and hormonal parameters in patients with polycystic ovary syndrome

Design

This study is carried out on 70 women with polycystic ovary syndrome who are less than 38 years old. Randomization is done through providing envelopes each containing 180 capsules. These envelopes are numbered based on random allocation table by someone outside the study. Afterwards, envelopes are handed to the doctor to give them to patients in turn.

Settings and conduct

This is a double-blinded clinical trial in which researcher and patient are unaware of the type of intervention and it is carried out in Qaem and Imam Reza hospitals in Mashhad on 70 women with polycystic ovary syndrome. Participants will be randomly (through computerized randomization) divided into intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Normal maturation; Thyroid test is within normal range; Having Rotterdam criteria for polycystic ovary syndrome; Patient's age is between 18 and 35; Not having a recent history of surgical treatment and other treatment for polycystic ovary syndrome. Exclusion criteria: Use of sex steroids (such as birth control pills, hormone therapy, androgenic drugs); Use of chemical or herbal medicine; Use of cigarettes or hookahs.

Intervention groups

Intervention group: patients daily receive two 500-mg chamomile capsules for 3 months. Control group: patients daily receive two placebo capsules (which are similar to chamomile capsules in color but without effective ingredient) for 3 months.

Main outcome variables

Induction of ovulation; changes in hormonal parameter of total testosterone.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170315033085N3**

Registration date: **2018-06-16, 1397/03/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-16, 1397/03/26**

Update count: **0**

Registration date

2018-06-16, 1397/03/26

Registrant information

Name

malihe afiat

Name of organization / entity

Mashhad medical school

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2608

Email address

afiatm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-07, 1396/11/18

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of chamomile on ovulation induction and hormonal and clinical parameters in patients with polycystic ovary syndrome

Public title

Investigation of the effect of chamomile on ovulation induction in patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Normal maturation Thyroid test is within normal range
Having Rotterdam criteria for polycystic ovary syndrome
Patient's age is between 18 and 35 Not having a recent history of surgical treatment and other treatment for polycystic ovary syndrome

Exclusion criteria:

Use of sex steroids (such as birth control pills, hormone therapy, androgenic drugs) Use of chemical or herbal medicine Use of cigarettes or hookahs

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done through providing drug-containing envelopes which are numbered based on random allocation table by someone outside the study. Afterwards, envelopes are handed to the doctor to give them to patients in turn.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blinded study in which researcher and patient are unaware of the type of intervention which means researcher and patient have no knowledge of the content of the envelope and treatment method.

Placebo

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

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

345 - 91357

Approval date

2017-11-07, 1396/08/16

Ethics committee reference number

IR.MUMS.fm.REC.1396.444

Health conditions studied**1****Description of health condition studied**

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Rate of ovulation induction in patients with polycystic ovary syndrome

Timepoint

Investigate of the ovarian follicles is done on 12th day of the first cycle and also on the 3rd and 12th days of the third cycle and in case of not having menstruation, at the end of 90th for all patinets.

Method of measurement

Transvaginal ultrasound

2**Description**

total testosterone rate

Timepoint

measuring testosterone rate at the beginning of the study (before intervention) and at the end of the study

Method of measurement

ELISA method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients daily receive two 500-mg chamomile capsules for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Patients daily receive two placebo capsules (which are similar to chamomile capsules in color but without effective ingredient) with similar dose for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Malihe Afiat

Street address

Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3802 2609

Email

afiatm@mums.ac.ir

2

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Azam Akbari Lor

Street address

Ghaem hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3801 2477

Email

Akbarila941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

345 - 91357

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Azam Akbari Lor

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Ghaem hospital, Ahmad Abad Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone
+98 51 3801 2477
Email
Akbarila941@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Malihe Afiat
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2609
Email
afiatm@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Malihe Afiat
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave

City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3802 2609
Email
afiatm@mums.ac.ir

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

All data can be shared after patients are made unidentifiable

When the data will become available and for how long

Data can be accessible 6 months after results are published

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes

Under which criteria data/document could be used

Carrying out analysis on data is permitted

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author

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

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments