

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Sep 2026

Comparison of the efficacy of herbal medicine (Mixture) with Clomiphene citrate in treatment of Poly-cystic ovary syndrome (PCOS) and fertility rate in infertile women referring to Tabriz Al-Zahra hospital.

Protocol summary

Study aim

evaluate the effects of herbal Mixture in infertile women with Polycystic ovary syndrome (PCOS).

Design

This single-blind randomized clinical trial the participants were divided into three groups (g1: Clomiphene Citrate (CC); g2: herbal mixture; and g3: herbal mixture along with (CC) by random allocation software through randomized blocks of three and six with an allocation ratio of 1:1:1. For allocation concealment, according to sequence generation opaque and sealed envelopes No; each contain a letter designating the allocation. The 1 envelope was dedicated to 1 participant and this process was followed to the end of the research. ample size was calculated based on three variables of MDA, Testosterone and HOMA-IR.

Settings and conduct

it was done in alzahra hospital ,TBZMED. All participants were informed about the purpose of the study, and an informed consent was obtained from each of them.

Participants/Inclusion and exclusion criteria

Inclusion: willing to participate in the study, having at least two out of three of the Rotterdam criteria (2003) for the diagnosis of PCOS, aged between 18–35 years old, having BMI less than 30, not receiving any treatment at least in the last 3 months. Exclusion: diabetes mellitus, use of medications such as those helping ovulation or insulin sensitizers, thyroid disorders, cholesterol-lowering drugs, smoking, Hypertension, cardiovascular diseases, Cushing syndrome, allergy to Mentha spicata , Zingiber officinale , Cinnamomum zeylanicum and Citrus Sinensis

Intervention groups

clomiphene citrate group from third- fifth day of menstruation for five days for three menstrual cycles; herbal mixture capsule group, herbal mixture capsule group along with CC for 3 months

Main outcome variables

Primary outcomes included serum levels of antioxidants blood biomarkers and sex hormones. Thyroid hormones and clinical features were considered as secondary outcomes.

General information

Reason for update

It was requested that some sections that were incomplete be completed.

Acronym

IRCT registration information

IRCT registration number: **IRCT201509295563N7**

Registration date: **2016-01-09, 1394/10/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-16, 1398/10/26**

Update count: **1**

Registration date

2016-01-09, 1394/10/19

Registrant information

Name

Elaheh Ouladsahebmadarek

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1554 1221

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madarek@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tabriz University Of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of herbal medicine (Mixture) with Clomiphene citrate in treatment of Poly-cystic ovary syndrome (PCOS) and fertility rate in infertile women referring to Tabriz Al-Zahra hospital.

Public title

The effects of herbal mixture in infertile women with Polycystic ovary syndrome (PCOS): a randomized controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

willing to participate in the study having at least two out of three of the Rotterdam criteria (2003) for the diagnosis of PCOS aged between 18–35 years old having body mass index (BMI) less than 30 not receiving any treatment at least in the last 3 months (wash out)

Exclusion criteria:

patients with diabetes mellitus use of medications such as those helping ovulation or insulin sensitizers thyroid disorders cholesterol-lowering drugs smoking hypertension cardiovascular diseases Cushing syndrome allergy to Mentha spicata (spearmint), Zingiber officinale (ginger), Cinnamomum zeylanicum (cinnamon), and Citrus Sinensis (sweet orange)

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were divided into three groups (group 1: Clomiphene Citrate (CC); group 2: herbal mixture; and group 3: herbal mixture along with (CC) by random allocation software through randomized blocks of three and six with an allocation ratio of 1:1:1. For allocation concealment, according to sequence generation opaque and sealed envelopes numbered; each contain a letter designating the allocation. The first envelope was dedicated to first participant and this process was followed to the end of the research. Only the statistician

was blind to the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistician was blind to the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University Of Medical Sciences

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South shareati Street

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Postal code

5138815941

Approval date

2015-10-03, 1394/07/11

Ethics committee reference number

TBZMED.REC.1394.576

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

Female infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

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

Treatment of ovarian cysts

Timepoint

Before the intervention, three months after intervention

Method of measurement

Ultrasound of the ovaries (ovarian size, number and size of follicles)

Secondary outcomes

1

Description

Pregnancy

Timepoint

3 months after taking medicinal plants (Citro Plus)

Method of measurement

Positive BhCG

Intervention groups

1

Description

" :Intervention group: " herbal medicine (Mixture) 700 mgs/day continuous for 3 cycles.

Category

Treatment - Drugs

2

Description

"Control group" Clomiphene Citrate 50-150 mg for 3 cycles

Category

Treatment - Drugs

3

Description

" :Intervention group: " herbal medicine (Mixture) 700 mgs/day continuous with Clomiphene Citrate 50-150 mg for 3 cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Women Health Reproduction Research Center

Full name of responsible person

Arash Khaki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Alireza Rashidi

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Third Floor, Central Building of Number2, Golgasht Street

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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

Vice chancellor for Research,Tabriz University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

PMC Pharmaceutical International Company

Full name of responsible person

Arash Khaki

Position

Prof. of Pathology

Latest degree

Ph.D.

Other areas of specialty/work

Pathology

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Person responsible for scientific inquiries

Contact

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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

age of patient

When the data will become available and for how long

September 2019

To whom data/document is available

Academic member of universities

Under which criteria data/document could be used

Ministry of Health and education

From where data/document is obtainable

Womens Reproductive Health Research Center Tabriz
University of Medical sciences , Dr Nava Ainehchi
00984135541221

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

Direct Contact to Womens Reproductive Health Research
Center Tabriz University of Medical sciences- 2 months

Comments