Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 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 toTabriz 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 1envelope 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)
Phone
+98 41 1554 1221
Email address
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 toTabriz 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
Street address
South shareati Street
City
Tabriz
Province
East Azarbaijan
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
Street address
South shareati Street
City
Tabriz
Province
East Azarbaijan
Postal code
5138815941
Phone
+98 51 3554 1221
Email
arashkhaki@yahoo.com
Web page address
https://wrhrc-en.tbzmed.ac.ir/

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
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3554 1221
Email
wrhrcenter@gmail.com
Web page address
https://wrhrc-en.tbzmed.ac.ir/
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
Street address
South shareati Street
City
Tabriz

Province
East Azarbaijan
Postal code
5138815941
Phone
+98 41 3555 6943
Fax
Email
arashkhaki@yahoo.com
Web page address
https://pmcpharma.org

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Elaheh Ouladsahebmadarek
Position
Prof. of Ob & Gyn
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Tabriz University Of Medical Sciences,Golgasht Street,
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3554 1221
Fax
Email
wrhrcenter@gmail.com
Web page address
https://wrhrc-en.tbzmed.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Elaheh Ouladsahebmadarek
Position
Prof. of Ob & Gyn
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Tabriz University Of Medical Sciences,Golgasht Street,
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
+98 41 3554 1221
Fax
Email
wrhrcenter@gmail.com
Web page address

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