

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison The Therapeutic Effect of Curcumin Nanomicelle And Metformin In Women With Polycystic Ovarian Syndrome

Protocol summary

Study aim

The Comparison Effect Of Curcumin Nanomicelle With Metformin In Treatment Of Women With Polycystic Ovary Syndrome

Design

Patients Were Randomly Divided Into Two Groups of 50 Each. The First Group Was Treated With Metformin Tablets (500 Mg, Three Times Daily) And The Second Group Treated With Metformin Tablets (500 Mg, Three Times Daily) And The Nanomicelle Curcumin (80 Mg) Once Daily For 12 Weeks

Settings and conduct

The Study Is A Single-Blind Clinical Trial Conducted At Shahid Sadoughi Hospital, And One Of The Treatment Centers Of Shahid Sadoughi University Of Medical Sciences, Lasting Three Months. Randomization Was Also Performed By Random Sequence Generation Software

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age, Observation Of Ovaries And Menstrual Cycle Exclusion Criteria: Use Of Certain Drugs And Specific Diseases In The Last 90 Days And A Number Of Emerging Clinical Conditions That Make Continuing Treatment Impossible And Immoral

Intervention groups

Determination And Comparison Of Laboratory Data And Complications Of Metformin And Curcumin Groups Before And After Treatment

Main outcome variables

Adverse drug reactions Nominal qualitative dependent variable; Continuous quantitative variable weight and BMI changes; Continuous quantitative dependent variable laboratory factors changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090422001836N11**

Registration date: **2019-09-21, 1398/06/30**

Registration timing: **retrospective**

Last update: **2019-09-21, 1398/06/30**

Update count: **0**

Registration date

2019-09-21, 1398/06/30

Registrant information

Name

Seyed Mojtaba Sohrevardi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1320 5001

Email address

smsohrevardi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison The Therapeutic Effect of Curcumin Nanomicelle And Metformin In Women With Polycystic Ovarian Syndrome

Public title

Comparison The Therapeutic Effect Of Curcumin Nanomicelle And Metformin In Women With Polycystic Ovarian Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages 18 to 40 Observe 12 Follicles Or More In Size Of 2-9 Mm In The Ovary By Ultrasound Oligomenorrhea or Amenorrhea In The Last 6 Months Testosterone Levels Above 0.7 ng/dl Serum Insulin Levels Above 16 U/ml

Exclusion criteria:

Pregnancy And Lactation During The Last 90 Days And Discontinuation Of Medication During Treatment Liver And Kidney Failure During The Last 90 Days And Discontinuation Of Medication During Treatment Thyroid Dysfunction During The Last 90 Days And Discontinuation Of Medication During Treatment Hyper Prolactinemia During The last 90 Days And Discontinuation Of Medication During Treatment Adrenal Dysfunction During The Last 90 Days And Discontinuation Of Medication During Treatment Congenital Adrenal Hyper Plasia During The Last 90 Days And Discontinuation Of Medication During Treatment Cushing's Syndrome During The Last 90 Days And Discontinuation Of Medication During Treatment Use Of Contraceptives During The Last 90 Days And Discontinuation Of Medication During Treatment Taking Estrogen And Progesterone In The Last 90 Days And Discontinuing Medication During Treatment Ovulation Induce Medication For The Last 90 Days And Discontinue Medication During Treatment Use Of Anti-Androgen Drugs During The Last 90 Days And Discontinuation Of Medication During Treatment Insulin Use During The Last 90 Days And Discontinuation Of Medication During Treatment

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

More than 1 sample in each individual

Number of samples in each individual: **50**
100

Randomization (investigator's opinion)

Randomized

Randomization description

Random Allocation Software Was Used For Block Randomization And RANUNI And RANNOR Functions Were Used To Generate Random Numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients And Statistics Experts Are Kept Blind In This

Study. It Should Be Noted That All Patients Received Current And Accepted Treatment For Their Disease, And No Patients Was Excluded From Conventional Treatment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Faculty of Pharmacy, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2017-11-29, 1396/09/08

Ethics committee reference number

IR.SSU.MEDICINE.REC.1396.195

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

Polycystic Ovary Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic Ovarian Syndrome

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

Serum Insulin Level

Timepoint

Before Intervention And After Intervention(After Three Month)

Method of measurement

μU/ml

2**Description**

Low Density Lipoprotein

Timepoint

Before Intervention And After Intervention(After Three Month)

Method of measurement

Mili Gram Per Deciliter

3**Description**

High Density Lipoprotein

Timepoint

Before Intervention And After Intervention(After Three Month)

Method of measurement

Mili Gram Per Deciliter

4**Description**

Triglyceride

Timepoint

Before Intervention And After Intervention(After Three Month)

Method of measurement

Milligram Per Deciliter

5**Description**

Fast Blood Sugar

Timepoint

Before Intervention And After Intervention(After Three Month)

Method of measurement

Milligram Per Deciliter

6**Description**

17hydroxyprogesterone

Timepoint

Before Intervention And After Intervention(after three month)

Method of measurement

Milligram Per Liter

7**Description**

Total Testosterone

Timepoint

Before Intervention And After Intervention(After Three Month)

Method of measurement

Microgram Per Liter

8**Description**

LH/FSH Ratio

Timepoint

Before Intervention And After Intervention(After Three Month)

Method of measurement

IU Per Liter

9**Description**

Cholesterol

Timepoint

Before Intervention And After Intervention(After Three Month)

Method of measurement

Milligram Per Deciliter

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group: The First Group (50 Patients) Treated With Metformin 500 Mg Three Times Daily (First Week 500 Mg Daily And Then Second Week 500 Mg Twice Daily And Third Week 500 Mg Three Times Daily And Continued With 500 Mg Three Times). Times Per Day For Three Months)

Category

Treatment - Drugs

2**Description**

Intervention Group: Second Group (50 patients) Treated With Metformin 500 Mg Three Times Daily (First Week 500 Mg Daily And Then Second Week 500 Mg Twice Daily And Third Week 500 Mg Three Times Daily And Continued With 500 Mg Three Times And Nano-Micelles Of Curcumin 80 Mg Once Daily For Three Months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sadoughi hospital

Full name of responsible person

Seyed Mojtaba Sohrevardi

Street address

Shahid Sadoughi hospital-Riazi Square- Safayieh

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Info@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Massoud Mirzai

Street address
Research Department, Building No 2, Yazd Shahid
Sadoughi University of Medical Sciences, Bahonar
Square, Yazd, Iran

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Phone
+98 35 3726 3733

Email
Education@ssu.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Faculty of Pharmacy- Shahid Sadoughi University of
Medical Sciences

Position
Dr Seyed Mojtaba Sohrevardi/Faculty of Pharmacy

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy- Shahid Sadoughi University of

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Seyed Mojtaba Sohrevardi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr Seyed Mojtaba Sohrevardi

Position
PhD of clinical pharmacy

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
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Medical Sciences- Shohadaye Gomnam boulevard-
Professor Hesabi boulevard- Yazd

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Yazd

Province

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Publishing patient information before publishing an article does not seem to be ethical

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available