Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 Lntervention 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
Mililgram Per Deciliter

5

Description
Fast Blood Suger
Timepoint
Before Intervention And After Intervention(After Three Month)
Method of measurement
Milligram Per Deciliter

6

Description
17hydroxyprogestrone
Timepoint
Before Intervention And After Intervention(after three month)
Method of measurement
Miligram 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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Email
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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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Postal code
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Phone
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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
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Person responsible for scientific inquiries

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Position
Associate professor
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Specialist
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Person responsible for updating data

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Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
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Street address
Faculty of Pharmacy- Shahid Sadoughi University of Medical Sciences- Shohadaye Gomnam boulevard- Professor Hesabi boulevard- Yazd
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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