Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of metabolic, endocrine, and clinical outcomes of treatment with simvastatin and metformin in women with polycystic ovaries

Protocol summary

Study aim
Comparison of metabolic, endocrine, and clinical outcomes of treatment with simvastatin and metformin in women suffering from PCOS

Design
In this study, 144 patients with polycystic ovaries with admission conditions referred to gynecology clinics of Shiraz University of Medical Sciences will be selected. Participants will be randomly divided into intervention and control groups.

Settings and conduct
This single-blind randomized clinical trial is conducted on all eligible patients with PCOS referring to gynecology clinics affiliated to Monash University of Medical Sciences during the study period After gaining the required permissions and application of ethical issues according to Helsinki's declaration, the researcher will refer to the clinics affiliated to Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria
All women referring to the gynecology clinics affiliated to Monash University of Medical Sciences who have PCOS based on Rotterdam criteria (having 2 of the following criteria: 1- oligomenorrhea or amenorrhea; 2- clinical or laboratory findings of hyperandrogenism and 3- existence of polycystic ovaries in ultrasound examination) will be invited to take part in the study

Intervention groups
The first group will receive 20 mg of wormatin every night after dinner and the second group will receive 500 mg of metformin three times daily after meals.

Main outcome variables
- Clinical parameters (hirsutism, acne, BMI, blood pressure, number of spontaneous menstrual cycles in a year, and ovarian volume) 2- Endocrine parameters (total testosterone, free testosterone, DHEA, estradiol, FSH, LH, SHBG, prolactin, and TSH) 3- Metabolic parameters (bilirubin, aminotransferases, total cholesterol, LDL, HDL, TG, fasting glucose, 2-hour glucose tolerance test, fasting insulin, insulin sensitivity index, hs-CRP, sVCAM, and homocysteine).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140525017827N8**
Registration date: **2020-04-10, 1399/01/22**
Registration timing: **prospective**

Last update: **2020-04-10, 1399/01/22**
Update count: **0**

Registration date
2020-04-10, 1399/01/22

Registrant information

Name
Nasrin Asadi

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 71 1233 2365

Email address
asadin@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-13, 1399/01/25

Expected recruitment end date
2020-07-15, 1399/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of metabolic, endocrine, and clinical outcomes of treatment with simvastatin and metformin in women with polycystic ovaries

Public title
Effect of metformin and simvastatin in treatment of polycystic ovarian syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
oligomenorrhea or amenorrhea clinical or laboratory findings of hyperandrogenism existence of polycystic ovaries in ultrasound examination) will be invited to take part in the study Aging 18-40 years single Not suffering from thyroid disorder, Cushing's syndrome, and hyperprolactinemia Not having kidney disorder, liver disorder, diabetes, and lipid profile disorder Not having the history of cardiovascular diseases and hypertension Not having used ovarian function stimulators or hormonal drugs during the past 3 months Not having used medications affecting insulin or lipid profiles within the past 3 months Not smoking Not consuming alcohol Not using drugs Not suffering from breast cancer Not having medical contraindications Not having maladaptation

Exclusion criteria:
Getting married Not being willing to continue treatment Presentation of side effects due to consumption of study medications Not following the research protocol Losing weight by 3 kg or more within the past 2 months

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software Minitab; Sequence Building: Using randomized 4 in 4 blocks; Hiding method: Use similar bottles

Blinding (investigator's opinion)
Double blinded

Blinding description
Metformin and simvastatin have been administered in the similar bottles, so patients and researchers were unable to detect which one was Metformin or simvastatin . Our nurse colleague in this study in Hafez hospital delivered formulations to the participants of the study according to the randomized block table. She was unaware of the content of the bottles. The researcher had no information about formulation used by each patient while visiting them. At the end of the study, the formulations were decoded and the patients assigned to each group were identified.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz

City
Shiraz

Province
Fars

Postal code
34786-71946

Approval date
2020-01-15, 1398/10/25

Ethics committee reference number
IR.SUMS.REC.1398.1246

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
Endocrine parameters (total testosterone, free testosterone, DHEA, estradiol, FSH, LH, SHBG, prolactin, and TSH)

Timepoint
before and after intervention

Method of measurement

Eliza Kit

2

Description
Metabolic parameters (bilirubin, aminotransferases, total cholesterol, LDL, HDL, TG, fasting glucose, 2-hour glucose tolerance test, fasting insulin, insulin sensitivity index, hs-CRP, sVCAM, and homocysteine).
Timepoint
Before and after intervention
Method of measurement
Eliza Kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receive 20 mg of simvastatin every night after dinner
Category
Treatment - Drugs

2

Description
Intervention group: receive 500 mg of metformin three times daily after meals
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez hospital of Shiraz University of Medical Sciences
Full name of responsible person
Maliehe kamali
Street address
Hafez Hospital; Shahid Chamran blvd
City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3612 8257
Email
malihe_kamali@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Yoones Ghasemi
Street address
Building of Shiraz University of Medical Sciences, Zand Ave
City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3235 7282
Email
ghasemiy@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maliehe Kamali
Position
Midwifer
Latest degree
Master
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Maternal- Fetal Medicine (Perinatology)research center; Hafez Hospital; Chamran Ave.,Shiraz
City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3612 8258

Email
malihe_kamali@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Nasrin Asadi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Maternal- Fetal Medicine (Perinatology) research center; Hafez Hospital; Chamran Ave., Shiraz
City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3612 8258
Email
nsasadi2012@yahoo.ca

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Nasrin Asadi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Maternal- Fetal Medicine (Perinatology) research center; Hafez Hospital; Chamran Ave., Shiraz
City
Shiraz
Province
Fars
Postal code
34786-71946
Phone
+98 71 3612 8258
Email
Nsasadi2012@yahoo.ca

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Participant data file: Information and research data Ethic form: Complete the Ethic form by the patient
When the data will become available and for how long
Participant data file:2020 Ethic form: 2020
To whom data/document is available
Participant data file: Researcher & Patient Ethic form: Patient
Under which criteria data/document could be used
Participant data file: participant's or legal guardian's are permitted for awareness of the results. Ethic form: participant's or legal guardian's are permitted for awareness of the results.
From where data/document is obtainable
Participant data file: Obstetrics and gynecology ward Shiraz university of medical sciences Ethic form: Obstetrics and gynecology ward Shiraz university of medical sciences
What processes are involved for a request to access data/document
Participant data file: Refer to Maternal Fetal medicine Research Center, request for result information. Ethic form: Refer to Maternal Fetal medicine Research Center, request for result information.
Comments