Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of the effect of two drugs, atorvastatin and glucophage, on plasma insulin resistance and follicular fluid changes (the amount of antioxidants and oocyte growth factors) in women with polycystic ovary syndrome.

Protocol summary

Study aim
A comparative study of the effect of two drugs, atorvastatin and glucophage, on plasma insulin resistance and follicular fluid changes (the amount of antioxidants and oocyte growth factors) in women with polycystic ovary syndrome.

Design
Clinical trial with a control group, randomized, phase 3 on 50 patients. The block method was used for randomization.

Settings and conduct
It was done in Zainbiah hospital in Shiraz and both groups took medicine orally for 6 weeks: the first group took 40 mg of atorvastatin every night after dinner, the second group took 500 mg of glucophage three times a day after meals.

Participants/Inclusion and exclusion criteria
Entry criteria: age 18-40 years, no thyroid disorder, Cushing's syndrome, hyperprolactinoma, no kidney disease, liver disease, diabetes, lipid profile disorder, no cardiovascular disease and blood pressure, no use of ovarian function stimulating drugs or hormonal drugs within 3 months. In the past, no use of insulin-sensitive drugs or lipid profile in the past 3 months, no smoking, no alcohol, no use of addictive substances, no breast cancer, no drug contraindications, no malabsorption, and minimal abnormal resistance to insulin. Exclusion criteria:Body mass more than 30 kg/m2 and body mass less than 19 kg/m2

Intervention groups
50 random samples will be selected and divided into two treatment groups: atorvastatin or case group (25) and glucophage or control group (25 people)

Main outcome variables
The effect of two drugs, glucophage and atorvastatin, on plasma insulin resistance: follicular fluid antioxidants: BMP15 and GDF9 levels in granulosa cells

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240122060763N1**
Registration date: **2024-02-01, 1402/11/12**
Registration timing: **prospective**

Last update: **2024-02-01, 1402/11/12**
Update count: **0**

Registration date
2024-02-01, 1402/11/12

Registrant information

Name
Sanaz Alaee

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3725 5699

Email address
alaee@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-22, 1402/12/03

Expected recruitment end date
2024-10-24, 1403/08/03

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effect of two drugs, atorvastatin and glucophage, on plasma insulin resistance and follicular fluid changes (the amount of antioxidants and oocyte growth factors) in women with polycystic ovary syndrome.

Public title
A comparative study of the effects of two drugs, atorvastatin and glucophage, on plasma insulin resistance and follicular fluid changes in women with polycystic ovary syndrome.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
According to the Rotterdam criteria (the presence of two criteria for the diagnosis of polycystic ovaries 1- oligomenorrhea or amenorrhea 2- clinical or laboratory findings of hyperandrogenism 3- the presence of polycystic ovaries in ultrasound examination) the diagnosis of PCOS has been confirmed in them Age 18-40 years Absence of thyroid disorder, Cushing's syndrome, hyperprolactinoma Absence of kidney disease, liver disease, diabetes, lipid profile disorder No history of cardiovascular disease and blood pressure Not using ovarian stimulation drugs or hormonal drugs in the last 3 months Not using insulin-sensitive drugs or lipid profiles in the last 3 months not smoking non-alcoholic No use of addictive substances Not having breast cancer Absence of medicinal contraindications Absence of malabsorption Having a minimally abnormal amount of insulin resistance
Exclusion criteria:
Body mass more than 30 kg/m2 Body mass less than 19 kg/m2
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The random assignment method in this study will be permutation block method in such a way that A represents the person who receives the case and B represents the person who receives the control. receives This method is implemented by considering blocks of 2 so that the total number of possible binary permutations is equal to 2. 2 blocks including: AB and BA. The desired random list of 50 items, which includes 25 blocks of 2 items (total number of samples = 50 x 25) is generated and the order of allocation of each of the methods to the samples participating in the study is determined. The way to use the table of random numbers is that a starting point is randomly selected and 25 numbers are randomly selected (row or column) and the permutation assigned to each number is noted (the order of placement of the permutations next to each other from left to right will be to the right) and how to allocate all 50 people to two groups A and B will be determined.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz Medical Sciences
Street address
Faculty of Modern Sciences, Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
7154895379
Approval date
2024-01-08, 1402/10/18
Ethics committee reference number
IR.SUMS.REC.1402.444

Health conditions studied

1

Description of health condition studied
Women with polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description

Primary outcomes

1

Description
The amount of insulin resistance is measured based on the HOMA index. The amount of fasting insulin is multiplied by the amount of fasting sugar and the

resulting number is divided by 22.5, which is equal to 1 in normal people.

Timepoint

The amount of insulin resistance is measured once before the intervention in two groups and again after the intervention in two groups

Method of measurement

Measuring insulin resistance: the amount of fasting insulin is multiplied by the amount of fasting sugar and the resulting number is divided by 22.5, which is equal to 1 in normal people.

Secondary outcomes

1

Description

Changes of MDA (malon-di-aldehyde) in follicular fluid

Timepoint

After the intervention, it is measured in the follicular fluid and compared with the standard value

Method of measurement

Using a commercial measuring kit of malondialdehyde kiazist

2

Description

Examination of TAC (Total Antioxidant Capacity) in follicular fluid

Timepoint

After the intervention and comparison with the standard value

Method of measurement

Using a commercial kit to measure TAC is key

3

Description

Investigation of catalase changes in follicular fluid

Timepoint

After the intervention and comparison with the standard value

Method of measurement

Using the commercial kit for measuring catalase of Kiazist company

4

Description

Measuring changes in oocyte growth factor (GDF-9) in granulosa cells

Timepoint

After the intervention and comparison with the standard value

Method of measurement

Through the expression of the gene of this protein with the help of Realtime PCR

5

Description

Changes in oocyte growth factor (BMP15) in granulosa cells

Timepoint

After the intervention and comparison with the standard value

Method of measurement

Through gene expression and Realtime PCR

Intervention groups

1

Description

Intervention group: Using atorvastatin in the amount of 40 mg every night after dinner for 6 weeks until the day of egg retrieval.

Category

Treatment - Drugs

2

Description

Control group: Taking 500 mg Glucophage 3 times a day after meals for 6 weeks until the day of egg retrieval.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zainabiya Hospital

Full name of responsible person

Dr. Sanaz Alaei

Street address

Unit 6،Third Floor،Reza Building 4،AllModares BoulevardeAzadegan Boulevard،y 5،

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hashem Hashempour

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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
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
Sanaz Alaee
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Reproductive Biology
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Person responsible for updating data

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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
There is no further information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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