

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Assesment the clinical effect of myoinositol on insulin resistance in women with PCOS

Protocol summary

Summary

Aim: assessment effect of myoinositol on insulin resistance in women with poly cystic ovarian syndrome. Drawings: the diagnosis of PCOS was based on the Rotterdam criteria, which necessitated 2 of the following 3 features: 1. oligoovulation and anovulation (less than 6 times in 12 months) 2. Clinical or biochemical signs of hyperandrogenism such as acne, alopecia or high androgen level 3. Polycystic ovaries on ultrasound examination. Design: The questionnaires were included height, weight, body mass index, waist, menstruation pattern, infertility, fasting glucose, fasting insulin, insulin resistance index, low density lipoprotein, high density lipoprotein, triglyceride, dehydroepiandrosterone, free testosterone were measured in these patients. Inclusion criteria: women who were between 20 and 40 years old, and had PCOS diagnosed by a gynecologist. Exclusion criteria: patients who were diagnosed with Cushing syndrome, congenital adrenal hyperplasia, hyperprolactinemia, hypothyroidism, hyperthyroidism, androgen secreting tumor, medications known to affect metabolic parameters, such as metformin and corticosteroid drugs, vitamin D, and serum calcium. Intervention: the patients received myoinositol 4 grams daily for 3 months and the pilot checked again three months after treatment. Written consent form was obtained from all patients. Primary outcome measure: fasting glucose, fasting insulin, HOMA IR. Secondary outcome measure: height, weight, body mass index, low density lipoprotein, high density lipoprotein, free testosterone, dehydroepiandrosterone, triglyceride.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010319426N4**

Registration date: **2015-01-17, 1393/10/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-17, 1393/10/27

Registrant information

Name

Saghar Salehpour

Name of organization / entity

Shahid Behshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2558

Email address

saghar.salehpour@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Healthparsian.co and Vice chancellor for research, Shahid Beheshti University of Medical Science

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2016-01-01, 1394/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment the clinical effect of myoinositol on insulin resistance in women with PCOS

Public title

Assesment the clinical effect of myoinositol on insulin resistance in women with PCOS

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: women who were between 20 and 40 years old, and had PCOS diagnosed by a gynecologist.
 Exclusion criteria: patients who were diagnosed with Cushing syndrome, congenital adrenal hyperplasia, hyperprolactinemia, hypothyroidism, hyperthyroidism, androgen secreting tumor; medications known to affect metabolic parameters, such as metformin and corticosteroids.

Age
 From **20 years** old to **40 years** old

Gender
 Female

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **50**

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Shahid Beheshti
 University of Medical Science

Street address

SBMU_ School of medicine, 3td floor, Velenjak ,
 Shahid Chamran highway, Tehran

City

Tehran

Postal code

193954719

Approval date

2014-11-20, 1393/08/29

Ethics committee reference number

SBMU.REC.1393.44

Health conditions studied

1

Description of health condition studied

Polycystic Ovarian Syndrome

ICD-10 code

E28.2

ICD-10 code description

Ovarian dysfunction, unspecified

Primary outcomes

1

Description

Fasting glucose

Timepoint

Before intervention and three months after treatment

Method of measurement

Blood serum

2

Description

Fasting insulin

Timepoint

Before intervention and three months after treatment

Method of measurement

Blood serum

3

Description

HOMA IR

Timepoint

Before intervention and three months after treatment

Method of measurement

Calculation by formula

Secondary outcomes

1

Description

Weight

Timepoint

Before intervention and three months after treatment

Method of measurement

Balance

2

Description

Height

Timepoint

Before intervention and three months after treatment

Method of measurement

Meter

3

Description

Body Mass Index

Timepoint

Before intervention and three months after treatment

Method of measurement

4**Description**

Low density lipoprotein

Timepoint

Before intervention and three months after treatment

Method of measurement

Blood serum

5**Description**

High density lipoprotein

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Blood serum

6**Description**

Free testosterone

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Blood serum

7**Description**

Dehydroepiandrosterone

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Blood serum

8**Description**

Triglyceride

Timepoint

Before intervention and two months after vitamin D injection

Method of measurement

Blood serum

Intervention groups1**Description**

Patients with diagnosis of PCOD under treatment with myoinositol (powder) 4 gram daily for three months and primary and secondary outcome measure before and after treatment

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Infertility & Reproductive Health Research Center
Shahid Beheshti University of Medical Science

Full name of responsible person

Zahra Sadeghzadeh

Street address

Taleghani hospital , Velenjak, Shahid Chamran
highway, Tehran

City

Tehran

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice chancellor for research, Shahid Beheshti
University of Medical Science

Full name of responsible person

Mrs Zahra Khateri

Street address

SBMU_ School of medicine, 3rd floor, Velenjak ,
Shahid Chamran highway, Tehran

City

Tehran

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, Shahid Beheshti University
of Medical Science

Proportion provided by this source**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty*2**Sponsor****Name of organization / entity**

Healthparsiian. com

Full name of responsible person

Melina Makhmour

Street address

Amirabad, tehran , Iran

City

Tehran

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Healthparsian. com

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Infertility & Reproductive Health Research Centre -
Shahid Beheshti of Medical Science

Full name of responsible person

Dr Saghar salehpour

Position

Associate professor

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for scientific inquiries

Contact

Name of organization / entity

Infertility & Reproductive Health Research Centre -
Shahid Beheshti of Medical Science

Full name of responsible person

Dr Sedighe Hosseini

Position

Gynecologist

Other areas of specialty/work

Street address