Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Evaluating the effect of sulforaphane supplementation in women with Polycystic ovary syndrome (PCOS) on depression, insulin resistance, and lipid profile change

Protocol summary

Study aim
Evaluating the effect of sulforaphane supplementation in women with Polycystic ovary syndrome (PCOS) on depression, insulin resistance, and lipid profile change

Design
Randomized double blind and placebo-controlled clinical trial

Settings and conduct
This study will be performed among women with PCOS who refer to the gynecology clinic of Arash Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of PCOS according to Rotterdam - Mild to moderate depression - 18-40 years old - BMI = or > 25 - High blood fat - Disruption of Glucose tolerance test. Exclusion criteria: Smoking - Lactation or gestation - Metabolic or thyroid dysfunction - Hyperprolactinemia - Hypercortisolemia - Severe depression - CNS drugs used such as antidepressants or anxiolytics - Insulin administration - Uncontrolled blood glucose level - Intense physical activity - History of severe stress - Emotional failure or hospitalization in recent past - History of mental health problems in first-degree relatives

Intervention groups
Intervention group: Women with PCOS take sulforaphane twice a day for 12 weeks. Control group: Women with PCOS take placebo twice a day for 12 weeks.

Main outcome variables
Severity of depression

General information

Reason for update
Length of time to complete the study

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N144**
Registration date: **2022-06-26, 1401/04/05**
Registration timing: **prospective**

Last update: **2026-06-03, 1405/03/13**
Update count: **3**

Registration date
2022-06-26, 1401/04/05

Registrant information

Name
Shahin Akhondzadeh

Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 5541 2222

Email address
s.akhond@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2025-10-02, 1404/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of sulforaphane supplementation in women with Polycystic ovary syndrome (PCOS) on

depression, insulin resistance, and lipid profile change

Public title
The effect of sulforaphane on depression in women with PCOS
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of PCOS according to Rotterdam Mild to moderate depression 18-40 years old BMI = or > 25 High blood fat Disruption of Glucose tolerance test
Exclusion criteria:
Smoking Lactation or gestation Metabolic or thyroid dysfunction Hyperprolactinemia Hypercortisolemia Severe depression CNS drugs used such as antidepressants or anxiolytics Insulin administration Uncontrolled blood glucose level Intense physical activity History of severe stress Emotional failure or hospitalization in recent past History of mental health problems in first-degree relatives
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups). The best way to create randomization is to use random allocation. Random allocation in clinical trial studies refers to the process of randomly dividing participants into different groups. Randomization gives each participant an equal chance to participate in each group. Successful randomization requires that researchers and study participants be unable to predict the type of intervention received.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Medicine Ethics Committee, Tehran University of Medical Sciences
Street address
School of Medicine, Tehran University of Medical Sciences, Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2022-03-28, 1401/01/08
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.157

Health conditions studied

1

Description of health condition studied
Severity of depression
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Severity of depression
Timepoint
Baseline and weeks 4, 8, & 12
Method of measurement
By Hamilton Depression Rating Scale (HDRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Women with PCOS take sulforaphane

15 mg twice a day for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Women with PCOS take placebo twice a day for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Dr. Ladan Kashani

Street address

Arash Hospital, Tehranpars, Tehran

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 8757

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kashani_ladan@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

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afotouhi@tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2023 to 2028

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Users should cite the resource of data

From where data/document is obtainable

Prof Shahin Akhondzadeh

What processes are involved for a request to access data/document

By E-mail

Comments