Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Evaluating the effect of inofolic supplementation on depression in Polycystic ovarian syndrome women with mild to moderate depression

Protocol summary

Study aim
Valuating the effect of inofolic supplementation on depression in Polycystic ovarian syndrome women with mild to moderate depression

Design
This study was designed as a single-blinded randomized clinical trial with parallel groups and a sample size of 106 people in each group.

Settings and conduct
The study will be conducted at Arash Women's Hospital on women with PCO. Patients who signed informed consent will be randomly divided into two groups. The first group received inofolic powder twice a day for 12 weeks and the second group did not receive any intervention. The level of depression is determined before and after the intervention and the changes in the level of depression are compared in the two groups. The evaluator of the results and the statistician are unaware of the type of intervention

Participants/Inclusion and exclusion criteria
Exclusion criteria: Smoking, Taking folate supplements in the last 3 months, Metabolic and thyroid disorders, Hyperprolactinemia, Hypercortisolemia, Severe depression, Use of drugs affecting, the nervous system (such as antidepressants and anti-anxiety drugs) , Insulin use, Lack of blood sugar control, Intense physical activity, Pregnancy, Lactation, History of mental health problems in first degree relatives, Other diseases in addition to depression

Intervention groups
Intervention group: Inofolic Powder twice daily for 12 weeks Control group: without intervention

Main outcome variables
Changes in the level of depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110731007165N11**
Registration date: **2020-12-25, 1399/10/05**
Registration timing: **prospective**

Last update: **2020-12-25, 1399/10/05**
Update count: **0**

Registration date
2020-12-25, 1399/10/05

Registrant information

Name
Ladan Kashani

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 8828 1866

Email address
kashani_ladan@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-09, 1399/10/20

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of inofolic supplementation on depression in Polycystic ovarian syndrome women with mild to moderate depression

Public title
Valuating the effect of inofolic supplementation on depression in Poly cystic ovarian syndrome women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18-40 years With mild to moderate depression BMI <= 30
Exclusion criteria:
Smoking Taking folate supplements in the last 3 months Metabolic and thyroid disorders Hyperprolactinemia Hypercortisolemia Severe depression Use of drugs affecting the nervous system (such as antidepressants and anti-anxiety drugs) Insulin use Lack of blood sugar control Intense physical activity Pregnancy Lactation History of mental health problems in first degree relatives, Other diseases in addition to depression
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization list (block randomization list)will be prepared by the statistician. Treatments will be placed in sealed envelopes and will be kept by the out-of-study nurse. After identification of the eligibility of the patient, the procedure will be explained to her and informed consent will be obtained. The intervention will be performed by the kind of intervention in the envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
Completion of the final information is up to the person who is unaware of the type of treatment and also the specialist will be blind. But the patient knows the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Qods St, Keshavarz Blvd, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2020-12-12, 1399/09/22
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.880

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32.8
ICD-10 code description
Other depressive episodes

Primary outcomes

1

Description
Changes in the level of depression
Timepoint
Before and after intervention
Method of measurement
Hamilton Depression Rating Scale (HDRS)

Secondary outcomes

1

Description
The blood tests for LDH,HDL,Total cholesterol ,TG, BMI, waist hip ratio , fasting glucose and insulin
Timepoint
Before and after the intervention
Method of measurement
The blood test

Intervention groups

1

Description
Intervention group: Inofolic Powder twice daily for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: Without intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women's hospital
Full name of responsible person
Dr. Ladan Kashani
Street address
No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3283
Email
Kashani_ladan@tums.ac.ir
Web page address
http://arash.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Sahraeiyan
Street address
Tehran University of Medical Sciences, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
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. Ladan Kashani
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Arash Hospital, Rashid Street, Tehran Pars
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3195
Fax
Email
Kashani_ladan@tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ladan Kashani
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Arash Hospital, Rashid Street, Tehran Pars
City
Tehran
Province
Tehran
Postal code
1653915981

Phone
+98 21 7788 3195
Fax
Email
Kashani_ladan@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ladan Kashani
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Arash Hospital, Rashid Street, Tehran Pars
City
Tehran
Province
Tehran
Postal code
1653915981
Phone
+98 21 7788 3195
Fax
Email
Kashani_ladan@tums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
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