Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

effect of magnesium supplementation on menstrual disorders, androgenic alopecia, quality of life and acne in women with poly cystic ovary syndrome

Protocol summary

Study aim

Determination and comparison of menstrual disorders,Androgenic alopecia,quality of life scores,the amount of acne, serum magnesium concentration, number of cysts in each ovary in the two groups of intervention and placebo before and after the intervention

Design

Clinical trial with control group, with parallel group, double-blind, randomized,Single phase on 70 patients . For randomization we use SPSS software version 25

Settings and conduct

70 women with PCOS referred to Al-Zahra and Shahid Beheshti hospitals in Isfahan will be divided into two groups of 35. The studied variables will be measured in all individuals, then for ten weeks one group with magnesium supplement and the other group with placebo. They will be supplemented bable blind method and after the supplementation period, the variables will be measured and examined again.

Participants/Inclusion and exclusion criteria

Women 18 to 45 years old with PCOS BMI between 5/18 to 30 Do not change the dose of the drug or start taking a new drug in the last two weeks Absence of menopause No hypothyroidism Do not take vitamin and mineral supplements

Intervention groups

Eligible written consent will be obtained from eligible individuals who wish to participate in the study. Individuals are also asked to complete a questionnaire on demographic information, medical history, and medications. Then, using SPSS software and based on the code assigned to each person, people are randomly divided into two groups of intervention and control. Using stratified randomization, the ratio of people with body mass index between 18.5 to 24.9 and people with body mass index between 25 and 29.9 will be the same in both groups.

Main outcome variables

Get magnesium supplements; Menstrual disorders; Androgenic alopecia; Acne; Quality of Life; Number of cysts; Serum magnesium levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130903014551N9**
Registration date: **2020-10-18, 1399/07/27**
Registration timing: **prospective**

Last update: **2020-10-18, 1399/07/27**
Update count: **0**

Registration date

2020-10-18, 1399/07/27

Registrant information

Name

Mohammad Hossein Rouhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3183

Email address

s_m_rouhani2003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
effect of magnesium supplementation on menstrual disorders, androgenic alopecia, quality of life and acne in women with poly cystic ovary syndrome

Public title
Effect of magnesium on poly cystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women 18 to 45 years old with PCOS BMI between 5/18 to 30 Do not change the dose of the drug or start taking a new drug in the last two weeks Absence of menopause Absence of hypothyroidism Do not take vitamin and mineral supplements
Exclusion criteria:
Failure to follow nutritional recommendations and interventions Failure to refer the person in the next steps Change the dose of the drug or start taking a new drug that affects the indicators of the study Having a specific disease that disrupts the study process Occurrence of menopause
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done through block randomization method (permuted blocked randomization). depending on the sample size , each block includes 4 characters and will be used AABB combination. In the following, all possible modes from the combination will be listed and a code will be allocated to each patient.
Blinding (investigator's opinion)
Double blinded
Blinding description
For double blinding of this study, at the beginning, cans contained magnesium supplement and placebo were coded as A and B by person other than researcher to ensure researcher and participants were not informed about types of supplement received by participants
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jarib St., Isfahan University of Medical Sciences and Health Services, Building No. 4 - Vice Chancellor for Research and Technology
City
esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-10-03, 1399/07/12
Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.406

Health conditions studied

1

Description of health condition studied
poly cystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Menstrual disorder
Timepoint
Before and after intervention
Method of measurement
Based on standard definitions provided by the International Federation of Gynecology and Obstetrics

2

Description
androgenic alopecia
Timepoint

Before and after intervention

Method of measurement

Sinclair Scale

3

Description

quality of life

Timepoint

Before and after intervention

Method of measurement

Health Survey Questionnaire (SF-36

4

Description

acne

Timepoint

Before and after intervention

Method of measurement

GAGS (global acne grading system) method

5

Description

Number of ovarian cysts

Timepoint

At the beginning and end of the intervention

Method of measurement

sonography

Secondary outcomes

1

Description

Physical activity

Timepoint

In the second,forth,sixth,eighth and tenth weeks

Method of measurement

Physical activity record questionnaire

2

Description

Dietary intake

Timepoint

In the second,forth,sixth,eighth and tenth weeks

Method of measurement

food record

3

Description

Serum magnesium concentration

Timepoint

At the beginning the intervention, In the fifth week of the intervention

Method of measurement

AAS method

Intervention groups

1

Description

Intervention group: Patients in this group will receive 250 mg magnesium supplement made by Donya Daru Sepehr Company once a day for 10 weeks.

Category

Treatment - Other

2

Description

Control group: Patients in this group will receive a placebo that contains starch and is made by Barij Essanss Company once a day for 10 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital of Isfahan

Full name of responsible person

Hatav Ghasemi Tehrani

Street address

soffe

City

isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 1668 5555

Fax

+98 31 1668 4510

Email

alzahra@mui.ac.ir

Web page address

http://alzahra.mui.ac.ir/oldsite/undefined/

2

Recruitment center

Name of recruitment center

shahid beheshti hospital of isfahan

Full name of responsible person

Hatav ghasemi tehrani

Street address

ostad motahari

City

isfahan

Province

Isfehan

Postal code

1234567891

Phone

+98 31 3236 7001

Email
info@manoshahr.ir

Web page address
http://manoshahr.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Shaghayegh Haghjoo Javanmard

Street address
hezar jarib

City
isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 8138

Fax
+98 31 3668 7898

Email
sh_haghjoo@med.mui.ac.ir

Web page address
http://research.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Mahsima Jaripur

Position
Executor of plan

Latest degree
Master

Other areas of specialty/work
Nutrition

Street address
sepah

City
kashan

Province
Isfehan

Postal code
8714683561

Phone
+98 31 5546 1381

Email
mahsimajaripur@ut.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mohamad Hossein Rohani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Food and nutrition faculty, Isfahan medical university, hezar jarib street, Isfahan, Iran

City
isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 0048

Email
s_m_rouhani2003@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mahsima Jaripur

Position
Executor of plan

Latest degree
Master

Other areas of specialty/work
Nutrition

Street address
SEpah

City
Kashan

Province
Isfehan

Postal code

8714683561

Phone

+98 31 5546 1381

Email

mahsimajaripur@ut.ac.ir

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