

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Oct 2022

### 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**

Isfahan

**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, fourth, sixth, eighth and tenth weeks

**Method of measurement**

Physical activity record questionnaire

**2**

**Description**

Dietary intake

**Timepoint**

In the second, fourth, 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**

Isfahan

**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**

Isfahan

**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**

Isfahan

**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**

Isfahan

**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**

Isfahan

**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**

Isfahan

**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