

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)

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+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,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

Isfahan

Postal code

8174675731

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Web page address

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2

Recruitment center

Name of recruitment center

shahid beheshti hospital of isfahan

Full name of responsible person

Hatav ghasemi tehrani

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ostad motahari

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isfahan

Province

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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

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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

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Person responsible for scientific inquiries

Contact

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Assistant Professor

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Mahsima Jaripur

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Latest degree

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Phone

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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