Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Investigating the effect of magnesium supplementation on stress and ovulation rate in infertile women with polycystic ovary syndrome

Protocol summary

Study aim
Determining the effect of magnesium supplementation on stress and ovulation rate in infertile women with polycystic ovary syndrome

Design
Clinical trial with control group, with parallel group, double-blind, randomized, www.sealedenvelope.com site was used for randomization.

Settings and conduct
All infertile women referred to the infertility center of Bent El Hoda Hospital in Bojnurd and with polycystic ovary syndrome and candidates for drug treatment. Eligible individuals will complete Newton's Infertility Stress and Demographic Questionnaires. Their height and weight are measured with a seca digital foot scale to calculate BMI. The 3-day food reminder questionnaire is given to volunteers who have a score higher than 46 on the infertility stress scale and have a BMI less than 35, in order to determine the daily intake of each person in terms of total energy, carbohydrates, magnesium, and calcium. , potassium and caffeine to be determined. Participants who receive magnesium diet less than 75% of RDA are referred to receive pills and perform ultrasound to confirm polycystic ovaries on the third day of their period.

Participants/Inclusion and exclusion criteria
Infertility for more than a year Not using medicinal compounds and supplements containing magnesium. Not taking anti-anxiety and sedative drugs. Body mass index less than 35, Magnesium intake less than 75% of the recommended dietary intake

Intervention groups
Each participant is given a package containing 112 tablets (magnesium/placebo) for 8 weeks and is advised to take two tablets daily from the same day. The intervention group will take magnesium supplements twice a day in the form of magnesium oxide tablets (each tablet contains 250 mg of elemental magnesium) and the control group will take placebo tablets for 8 weeks.

Main outcome variables
Determining the rate of stress and ovulation following magnesium supplementation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091229002924N3**
Registration date: **2024-01-17, 1402/10/27**
Registration timing: **prospective**

Last update: **2024-01-17, 1402/10/27**
Update count: **0**

Registration date
2024-01-17, 1402/10/27

Registrant information

Name
Maryam Hassanzadeh Bashtian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3151 1206

Email address
m.h.bashtian@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2024-12-05, 1403/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Investigating the effect of magnesium supplementation on stress and ovulation rate in infertile women with polycystic ovary syndrome

Public title
Investigating the effect of magnesium supplementation on stress and ovulation
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Infertility for more than a year Absence of acute and chronic diseases, Not using medicinal compounds and supplements containing magnesium. Not taking anti-anxiety and sedative drugs. Not using drugs, tobacco and alcohol. Not using relaxation techniques. Body mass index less than 35, Magnesium intake less than 75% of the recommended dietary intake
Exclusion criteria:
Pregnancy, Use of oral contraceptive pills, Occurrence of any severe stress (for example, divorce or death of a relative), Personal desire to withdraw from the study during the study, Consumption of less than 90 out of 112 magnesium supplement tablets or placebo.
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation of samples to intervention and placebo groups will be done using the random block method with blocks of 4 and using the website www.sealedenvelope.com. In this study, with a ratio of 1:1, the samples will be divided into intervention and placebo groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to hide the random allocation, sealed opaque envelopes with a random sequence will be used among the selected people to enter the two groups. Also, in the implementation of the random allocation process, the person involved in the creation of the randomization program will be separate from other researchers to reduce the possible bias of the person creating the random sequence.In order to blind the study, before the start of the study, a set of cans containing the relevant tablets (magnesium tablets) and placebo (containing Avicel and lactose), which are completely similar to magnesium tablets in terms of shape, size and color, and manufactured by Sina Pharmaceutical Company was coded by a person other than the researcher as A (intervention group) and B (placebo group) to ensure that the researcher did not know the type of pills received in each group. Each participant is given a package containing 112 tablets (magnesium/placebo) for 8 weeks and is advised to take two tablets daily from the same day. The intervention group will take magnesium supplements twice a day in the form of magnesium oxide tablets (each tablet contains 250 mg of elemental magnesium) and the control group will take placebo tablets for 8 weeks. In order not to inform the participants of the study, magnesium supplement tablets and placebo will have similar appearance and at the first glance of an expert, they will look completely identical.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee of North Khorasan University of Medical Sciences
Street address
Shahid Vaghefi street. Dolat Blvd. North Khorasan University of Medical Sciences.
City
Bojnurd
Province
North Khorasan
Postal code
74877-94149
Approval date
2023-12-27, 1402/10/06
Ethics committee reference number
IR.NKUMS.REC.1402.141

Health conditions studied

1

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

Primary outcomes

1

Description
To determine the effect of magnesium supplementation on stress and ovulation rate in infertile women with polycystic ovary syndrome
Timepoint
Newton's stress questionnaire first and then 4 weeks after taking the pills and at the end of taking the pills.Vaginal ultrasound at the beginning of the study as an entry criterion and then 4 weeks after taking the pills and then between the 10th and 14th day of the trigger drug cycle.
Method of measurement
Ultrasound, Newton stress questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group receives magnesium supplements twice a day in the form of magnesium oxide tablets (each tablet contains 250 mg of elemental magnesium).
Category
Treatment - Drugs

2

Description
Category
empty

3

Description
Control group: The control group will take placebo pills for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Department of Bent Al Hoda Hospital. Bojnord city
Full name of responsible person
Maryam Hassanzadeh Bashtian
Street address
Dolat Blvd. Shahid Waghefii St. North Khorasan University of Medical Sciences, second floor.
City
Bojnurd
Province
North Khorasan
Postal code
74877-94149
Phone
+98 58 3151 3001
Email
m.h.bashtian@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Bahram Bibak
Street address
Shahriyar St. Vice Chancellor of University Research and Technology.
City
Bojnurd
Province
North Khorasan
Postal code
9417694780
Phone
+98 58 3151 1420
Email
bibak44@googlemail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
Maryam Hassanzadeh Bashtian
Position
Faculty member
Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health
Street address
Shahriyar St. school of Nursing. Midwifery Department.
City
Bojnurd
Province
North Khorasan
Postal code
94176-96786
Phone
+98 58 3229 7097
Email
m.h.Bashtian@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Maryam Hassanzadeh Bashtian
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Shahriyar St. School of Medicinie & Nursing . Midwifery Department.
City
Bojnurd
Province
North Khorasan
Postal code
94176-96786
Phone
+98 58 3229 7097
Email
m.h.bashtian@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Maryam Hassanzadeh bashtian
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Shahriyar St. School of Medicine & Nursing. Midwifery Department.
City
Bojnurd
Province
North Khorasan
Postal code
94176-96786
Phone
+98 58 3229 7097
Email
m.h.bashtian@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available