

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Magnesium supplementation on patients' depression and anxiety and sleep quality after cardiac surgery

Protocol summary

Study aim

Investigating the effect of magnesium supplementation on anxiety and depression and sleep quality

Design

This research will be performed as double-blind clinical trial on CABG candidate patients hospitalized in Jamaran hospital. Patients will be selected by available sampling method and will be randomly assigned to both intervention and control groups.

Settings and conduct

This research will be performed by double-blind clinical trial on CABG candidate patients admitted to Jamaran Hospital in Tehran.

Participants/Inclusion and exclusion criteria

The criteria for admission were: CABG candidate patients admitted to Jamaran Hospital. Younger than 70 years- without having atrial fibrillation Lack of developing nausea-vomiting-without having to kidney failure and liver-no history of transient ischemic attack and ischemic stroke within the last month Exclusion criteria were as follows: emergency surgery, supplement sensitivity, history of sleep disorders, anxiety, and depression.

Intervention groups

Intervention group: Magnesium supplementation. Control group (Placebo): Starch

Main outcome variables

sleep quality ; anxiety and depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200523047556N1**

Registration date: **2020-07-04, 1399/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-04, 1399/04/14**

Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

Sara Saba

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4452 4511

Email address

samansayeh8594@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Magnesium supplementation on patients' depression and anxiety and sleep quality after cardiac surgery

Public title

Magnesium in depression and anxiety and sleep quality

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age less than 70 years Candidate for coronary artery

bypass graft surgery No atrial fibrillation (normal sinus)
No nausea and vomiting No liver and kidney failure No
history of stroke or cerebral ischemic attack in one
month

Exclusion criteria:

No willingness to participate in the study Emergency
surgery Acute renal failure during the study Respiratory
after surgery and the need for re-intubation inside the
chip Chronic diarrhea Sensitivity to supplements History
of sleep disorders, anxiety and depression

Age

To **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to the
intervention and control groups using block
randomization. Arrangement of the randomization
process: 1) Determining the volume of each block
(quadruple blocks) 2) Preparing the list of the blocks and
assigning a number (between 1 and 6) to each of them
3)Choosing random numbers between 1 and 6 4)
Defining the treatment assignment list

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the statistician and patients do not know
which group has received magnesium and which group
has received placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah Educational and
Medical Center

Street address

No.3,24 Ave, Tehransar Blvd.,Tehran

City

Tehran

Province

Tehran

Postal code

1388648736

Approval date

2020-01-04, 1398/10/14

Ethics committee reference number

IR.BMSU.BAQ.REC.1398.029

Health conditions studied

1

Description of health condition studied

Other functional disturbances following cardiac surgery

ICD-10 code

I97.1

ICD-10 code description

I97.1

Primary outcomes

1

Description

Sleep quality

Timepoint

Measuring the quality of sleep before prescribing
magnesium supplements the day after surgery and the
day of discharge from the hospital.

Method of measurement

Pittsburgh questionnaire

2

Description

Anxiety

Timepoint

Measuring the anxiety and before prescribing
magnesium supplements the day after surgery and the
day of discharge from the hospital.

Method of measurement

Anxiety Questionnaire

3

Description

Depreesion

Timepoint

Measuring depression before prescribing magnesium
supplements the day after surgery and the day of
discharge from the hospital.

Method of measurement

Depreesion Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Receiving 250 mg of magnesium oxide supplement tablets per day for 5 days from the time of hospitalization to the day of discharge. Magnesium tablets prepared by Wardavard Pharmaceutical Co.

Category

Prevention

2

Description

Control group: Starch drug preparation prepared by Verdavard Pharmaceutical Company: (Ovisil 100) for 5 days daily, two from the first day of hospitalization to the day of discharge

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Jamaran Hospital

Full name of responsible person

Sara Saba

Street address

Jamaran Heart Hospital ,Shahid Hassani Alley, Kia, Ave,Jamaran Square, Jamaran St,Tajrish Square, Tehan

City

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1977916773

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samansayeh8594@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Sara Saba

Street address

Mulla Sadra Street Vanak Square Tehran

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Tehran

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1435915371

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Sara Saba

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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No. 3, Unit 3, Unit 5, 24 Tehran St., Tehran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Position
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Latest degree
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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