

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effect of oral MgSo4 administration on plasma, inflammation marker, anti oxidant capacity, lysyl peroxidase, SIRT1, p53, eNOSox-LDL, LOX-1 levels and lipid profiles in atherosclerosis patients

Protocol summary

Study aim

Effect of MgSo4 on atherosclerosis

Design

This study is a double blind clinical trial which will be done on 100 patients. The participants will be divided into the two groups, Mg-treated group (300 mg MgSo4 daily) and control group (received placebo). The patients and personnel are blind to group assignment. Only the study analyst see unblinded data, but is not in contact with the participants.

Settings and conduct

This study will be done in Angiography department in Shahid Mohammadi hospital in Bandar Abbas. The patients and personnel will be blind to group assignment. Only the study analyst see unblinded data, but is not in contact with the participants.

Participants/Inclusion and exclusion criteria

The inclusion criteria: 1- Patients above 55 for women and 45 for men with moderate CAD The exclusion criteria: 1- Women under age 55, patients received Mg and Ca supplements, patients with left main lesion 2- patient with cancer or allergy, inflammation, patient with history of drug allergy, patient received immunosuppressive medications 3- Patients who had known kidney diseases and their serum creatinin above 1.5 mg/dl , raised hepatic enzymes above 3 folds over normal range, alcoholic patients, pregnant 4. Patients with current MI or CVA and patient with hypothyroidism or hyperthyroidism

Intervention groups

Patients with moderate CAD with atherosclerotic plaque less than 69% who are not candidate for angioplasty will be selected and will be divided into the two groups. Then blood and urine samples will be taken in order to determine the indexes every three months. Systolic and diastolic blood pressure, heart rate, weight, height, waist and hip circumference also will be measured every three

months.

Main outcome variables

Lipid profile, plasma oxLDL level and LOX1 gene . plasma inflammation marker and its gene expression, anti oxidant capacity, and plasma lysyl peroxidase level.

General information

Reason for update

Add more related indexes to atherosclerosis

Acronym

IRCT registration information

IRCT registration number: **IRCT20151028024756N3**

Registration date: **2018-07-28, 1397/05/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-16, 1398/09/25**

Update count: **2**

Registration date

2018-07-28, 1397/05/06

Registrant information

Name

Nepton Soltani

Name of organization / entity

Hormozgan University of Medical Science

Country

Iran (Islamic Republic of)

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Email address

nsoltani@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral MgSo4 administration on plasma, inflammation marker, anti oxidant capacity, lysyl peroxidase, SIRT1, p53, eNOSox-LDL, LOX-1 levels and lipid profiles in atherosclerosis patients

Public title

Effect of oral MgSo4 administration on plasma, inflammation marker, anti oxidant capacity, lysyl peroxidase, ox-LDL, LOX-1 levels and lipid profiles in atherosclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Moderate coronary artery disease<60 -2. Age of women and men should be more than 55 years and 45 years respectively. 3.Also people that are diabetic, hypertension, hyperlipidemia , smoker and insulin resistance will be entered in the study.

Exclusion criteria:

1.Age of women be less than 55 years,2. pregnant women3. patients who are using magnesium and calcium containing supplements 4. patients who have experienced renal insufficiency (serum creatinine levels more than 1.3 mg/dl in women and more than 1.5 mg/dl in men). 5- elevated hepatic enzymes (more than 3 folds over normal values),recent infections (less than one month prior to study) and chronic inflammatory diseases, cerebrovascular accident(CVA), also cancer and drug sensitivity

Age

From **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Only one of the researchers who are not involved in data

analyzing and not related to the patient treatment is responsible for dividing patients between the two groups

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Hormozgan University of Medical Sciences

Street address

Emam Hossein Blv. Faculty of Medicine, Hormozgan University of Medical Science

City

bandar abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2018-11-23, 1397/09/02

Ethics committee reference number

IR.HUMS.REC.1397.019

Health conditions studied**1****Description of health condition studied**

Patients with high blood pressure and Hyperlipidemic with a small plaque in one of the coronary arteries

ICD-10 code

I25.10

ICD-10 code description

Atherosclerotic heart disease of native coronary artery without angina pectoris

Primary outcomes**1****Description**

Hypertension- Hyperlipidemic- Atherosclerosis

Timepoint

every three months

Method of measurement

Barometer device and appropriate kits

Secondary outcomes

1

Description

Size of Atherosclerosis plaque

Timepoint

After one year

Method of measurement

With Angiography if patient satisfies

Intervention groups

1

Description

Patients with CAD (moderate coronary artery disease) under 60% who will chose for intervention group after angiography. For all patients, the demographic information, the records of the disease and the medications they use are filled and collected from the patients. The weight, blood pressure, waist and hip circumference of the patient are checked and blood sample will be taken to measure lipid profile, plasma oxLDL level and LOX1 gene expression. . Along with their routine treatment they will receive 300 mg/ day of oral magnesium sulfate from Neyak Company, which is taken with food for one year and they will follow up every three months. Blood samples are taken at each visit from the patient to measure the variables, the patient's weight, blood pressure, waist and hip circumference are also checked.

Category

Treatment - Drugs

2

Description

Control group: Patients with CAD under 60% who also will chose after angiography for control group. For all patients, the demographic information, the records of the disease and the medications they use are filled and collected and blood sample will be taken to measure lipid profile, plasma oxLDL level and LOX1 gene expression . This group will receive placebo which is made by Neyak Corporation with the same shape as intervention group. These patients are also followed up once every three months for a period of one year. In each visit, blood sample will be taken to measure study's variables and blood pressure, weight, waist and hip circumference of the patient will be checked.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Dr Hossain Farshidi

Street address

Islamic republic blv

City

Bandar Abbas

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Hormozgan

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123456789

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solnep2002@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Nepton Soltani

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Hezar Jareeb St

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Isfahan

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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

Bandare-abbas University of Medical Sciences

Proportion provided by this source

60

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

Nepton Soltani

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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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

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available