

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The evaluation of the effect of Magnesium Oxide on Improvement of Carotid intima media Thickness in hemodialysis patients in Alzahra & Khorshid hospitals in 1388-1389

Protocol summary

Summary

In end stage renal disease the lack of kidney function efficiency lead to toxic substances accumulate in the body, and patients should use kidney replacement treatments to dispose toxic agents frequently via hemodialysis. In these patients, inflammatory reaction lead to an increase in the frequency of vascular disease, especially atherosclerosis so the most important cause of mortality in these patients are heart failure and cardiovascular events. The ways in which the inflammatory process can delay or improve the process, will be able to improve the disease and longer the life of these patients. Use of magnesium supplements as one of the methods of postponing this process is considered. Measurement the thickness of media and intima of carotid with Doppler ultrasound is a valid method for assessment of atherosclerosis. In this study, patients with ESRD that are on hemodialysis at least 3 months, over 18 years old, without heart failure class 4 or CABG & transplantation plan, noncompliance or magnesium level more than 4mg/dl, receive magnesium oxide in Alzahra hospital. In our study we examine 27 patients in drug group & 27 patients in placebo group for 6 months and measure carotid IMT prior and after study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808202370N4**
Registration date: **2010-04-24, 1389/02/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-24, 1389/02/04

Registrant information

Name

Mojgan Mortazavi

Name of organization / entity

Isfahan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2009-08-22, 1388/05/31

Expected recruitment end date

2010-02-19, 1388/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of Magnesium Oxide on Improvement of Carotid intima media Thickness in hemodialysis patients in Alzahra & Khorshid hospitals in 1388-1389

Public title

The effect of Magnesium Oxide on Improvement of Carotid intima media Thickness in hemodialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusions: 1- Age \geq 18 2- Not having class IV heart failure 3- No history of CABG 4- No history of recent chemotherapy for malignancy 5- Serum PTH $>$ 100 6- Serum Mg $>$ 1.6 $<$ 4 mg/dl 7- Not consuming drugs containing Mg, Ca Channel Blockers, Cholesterol, during 3 months before study 8- Patients with ESRD on maintenance hemodialysis ($>$ 3 mo) 9- Not having uncontrolled HTN 10- Not being in transplantation schedule in the following 6 months Exclusions: 1- No compliance 2- Severe side effects 3- Serum Mg $>$ 4 mg/dl 4- Transplantation

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Vice Chancellor for Research, Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2017-11-21, 1396/08/30

Ethics committee reference number

388128

Health conditions studied

1

Description of health condition studied

End Stage Renal Disease

ICD-10 code

N18.0

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

Carotid Intima Media Thickness

Timepoint

Before & After Intervention

Method of measurement

Ultrasound Scan

Secondary outcomes

1

Description

Serum Ca

Timepoint

Before & After Intervention

Method of measurement

Autoanalyser

2

Description

serum phosphorus

Timepoint

Before & After Intervention

Method of measurement

Autoanalyser

3

Description

serum albumin

Timepoint

Before & After Intervention

Method of measurement

Autoanalyser

4

Description

serum PTH

Timepoint

Before & After Intervention

Method of measurement

Gama Counter

5

Description

serum magnesium

Timepoint

Before, monthly & After Intervention

Method of measurement

Autoanalyser

6

Description

serum TG

Timepoint

Before & After Intervention

Method of measurement

Autoanalyser

7

Description

serum total cholestrol

Timepoint

Before & After Intervention

Method of measurement

Autoanalyser

8

Description

serum HDL

Timepoint

Before & After Intervention

Method of measurement

Autoanalyser

9

Description

serum LDL

Timepoint

Before & After Intervention

Method of measurement

Autoanalyser

10

Description

serum bicarbonate

Timepoint

Before & After Intervention

Method of measurement

Autoanalyser

11

Description

serum CRP

Timepoint

befoe & after intervention

Method of measurement

ELISA

Intervention groups

1

Description

Tab Magnesium Oxide 440mg every two days for 6 months.

Category

Treatment - Drugs

2

Description

Placebo pill the same as intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis Unit, Alzahra Hospital

Full name of responsible person

dr firooze moinzadeh

Street address

City

Isfahan

2

Recruitment center

Name of recruitment center

Hemodialysis Unit, Khorshid Hospital

Full name of responsible person

dr firooze moinzadeh

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research

Street address

Vice Chancellor for Research, Isfahan University of Medical Sciences

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Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mojgan Mortazavi

Position

Assistant Prof. Nephrology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty