

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Changes of blood pressure and hemodynamic parameters after oral magnesium supplementation in patients with essential arterial hypertension

Protocol summary

Summary

Objectives: The objective of this study was to examine the changes of blood pressure and hemodynamic parameters after oral magnesium supplementation in patients with essential arterial hypertension. **Design:** Single arm study on 48 subjects, not blinded, intervention with magnesium oral supplementation. **Settings and conduct:** The participants took magnesium-supplementation for one month at home and had their blood pressure and hemodynamic parameters measured in hospital settings before and after the intervention. The measurements were performed with sphygmomanometer and impedance cardiography. **Participants:** Patients with essential arterial hypertension, aged 24-65, with unchanged antihypertensive therapy for at least one month. The exclusion criteria were: renal diseases, gastrointestinal diseases, diabetes mellitus, diseases of adrenal, thyroid and parathyroid glands, angina pectoris, congestive heart failure, aortic coarctation, food and drugs allergy, pregnancy, lactation, myocardial infarction, coronary revascularisation, transitory ischemic attack, oral intake of magnesium supplements in the last one month. **Intervention:** Daily oral supplementation with 300 mg magnesium in the form of magnesium-oxide granules ("Magnezijum 300 Direkt", Hermes Arzneimittel GmbH, Germany) during one month at home. **Primary outcome measures:** blood pressure; heart rate; thoracic fluid content (L/kOhm); stroke volume (the amount of pumped blood during each systole, mL); stroke index (normalized for body surface area, mL/m²); cardiac output (minute volume of heart, L/min); cardiac index (normalized for body surface area, L/(min*m²)); acceleration index (peak acceleration of blood flow in the aorta, 1/100/s²); left cardiac work index (normalized for body surface area, kg*m/m²); systemic vascular resistance index (normalized for body surface area, dyn*s*m²/cm⁵).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081535716N1**
Registration date: **2017-09-22, 1396/06/31**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-22, 1396/06/31

Registrant information

Name

Nikolina Banjanin

Name of organization / entity

Institute of Hygiene and Medical Ecology, Faculty of Medicine, University of Belgrade

Country

Serbia and Montenegro

Phone

00381 11 3612 762

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Recruitment status

Recruitment complete

Funding source

None

Expected recruitment start date

2014-09-17, 1393/06/26

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Changes of blood pressure and hemodynamic parameters after oral magnesium supplementation in patients with essential arterial hypertension

Public title

Changes of blood pressure and hemodynamic parameters after oral magnesium supplementation in patients with essential arterial hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 24-65; essential arterial hypertension; unchanged antihypertensive therapy for at least one month; Exclusion criteria: renal diseases, gastrointestinal diseases, diabetes mellitus, diseases of adrenal, thyroid and parathyroid glands, angina pectoris, congestive heart failure, aortic coarctation, food and drugs allergy, pregnancy, lactation, myocardial infarction, coronary revascularisation, transitory ischemic attack, oral intake of magnesium supplements in the last one month

Age

From **24 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

None

Secondary Ids**1****Registry name**

-

Secondary trial Id

-

Registration date

empty

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

Ethics Committee of the Faculty of Medicine,
University of Belgrade

Street address

Dr Subotica 8

City

Belgrade

Postal code

11000

Approval date

2015-07-01, 1394/04/10

Ethics committee reference number

29/VII-16

2**Ethics committee****Name of ethics committee**

Ethics Committee of the Clinical Center Of Serbia

Street address

Pasterova 2

City

Belgrade

Postal code

11000

Approval date

2014-09-16, 1393/06/25

Ethics committee reference number

1322/1

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

Essential (primary) hypertension

ICD-10 code

I10

ICD-10 code description

High blood pressure, Hypertension
(arterial)(benign)(essential)(malignant)(primary)(systemic)

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

Blood pressure (mm Hg)

Timepoint

Before and after intervention

Method of measurement

Sphygmomanometer and Impedance cardiography

2**Description**

Heart rate (beats per minute)

Timepoint

Before and after intervention

Method of measurement

Impedance cardiography

3**Description**

Thoracic fluid content (L/kOhm)

Timepoint

Before and after intervention

Method of measurement

Impedance cardiography

4**Description**

Stroke Volume (mL)

Timepoint

Before and after intervention

Method of measurement

Impedance cardiography

5**Description**Stroke index (mL/m²)**Timepoint**

Before and after intervention

Method of measurement

Impedance cardiography

6**Description**

Cardiac output (L/min)

Timepoint

Before and after intervention

Method of measurement

Impedance cardiography

7**Description**Cardiac index (L/(min*m²))**Timepoint**

Before and after intervention

Method of measurement

Impedance cardiography

8**Description**Acceleration index (L/100/s²)**Timepoint**

Before and after intervention

Method of measurement

Impedance cardiography

9**Description**Left cardiac work index (kg*m/m²)**Timepoint**

Before and after intervention

Method of measurement

Impedance cardiography

10**Description**Systemic vascular resistance index (dyn*s*m²/cm⁵)**Timepoint**

Before and after intervention

Method of measurement

Impedance cardiography

Secondary outcomes**1****Description**

-

Timepoint

-

Method of measurement

-

Intervention groups**1****Description**

Daily oral supplementation with 300 mg of magnesium in the form of magnesium-oxide granules ("Magnezijum 300 Direkt" Hermes Arzneimittel GmbH, Germany) during one month at home. The granules were dissolved in the mouth with no liquid.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

The Multidisciplinary Center for Polyclinic Diagnostics , Assessment and Treatment of Blood Pressure

Full name of responsible person**Street address****City**

Belgrade

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

-

Full name of responsible person

-

Street address

-

City

-

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
-
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
Institute of Hygiene and Medical Ecology, Faculty of Medicine, University of Belgrade
Full name of responsible person
Nikolina Banjanin
Position
Teaching Assisstant/MD
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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