The effects of magnesium on vascular stiffness: a long-term study in healthy overweight and slightly obese men and women.

Published: 27-08-2014
Last updated: 21-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lipid metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON42248

Source
ToetsingOnline

Brief title
Magnesium and Vascular Stiffness

Condition

- Lipid metabolism disorders

Synonym
Insulin Resistance Syndrome, Metabolic Syndrome, Syndrome X

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: TI Food and Nutrition

Intervention

Keyword: Magnesium, Vascular stiffness

Outcome measures

Primary outcome

The primary endpoint is the difference in response on vascular stiffness

measured from carotid-femoral PWV:

Between overweight and slightly obese participants that received magnesium

citrate (total daily dose: 350 mg elemental magnesium) or a placebo for 24

weeks

Secondary outcome

Secondary endpoints are effects and changes over time of an increased magnesium

intake on BP, other markers reflecting vascular function (e.g. pulse wave

analysis (PWA), flow-mediated dilation (FMD), finger peripheral arterial

tonometry (PAT) and microvascular diameters), and plasma biomarkers related to

low-grade inflammation and vascular activity.

Study description

Background summary

Observational epidemiologic studies have observed an inverse relationship between daily dietary magnesium intake and blood pressure (BP). Except for BP, magnesium may also beneficially affect other cardiovascular risk markers. Whether all these effects translate into improved vascular function is not known. Different vascular function markers at various stages on the pathway between diet and disease exist. One of these markers, vascular stiffness, is

closely related to the process of atherosclerosis, an independent cardiovascular risk factor, and predictive of future cardiovascular events and mortality. To examine the integrated effects of interventions on cardiovascular risk, vascular stiffness may therefore serve as a marker at the later stage of cardiovascular disease development.

Study objective

Considering the background information given in the previous paragraph, the following research question has been formulated:

What is the long-term (24 weeks) effect of magnesium citrate (total daily dose: 350 mg elemental magnesium) on vascular stiffness measured from carotid-femoral pulse wave velocity (PWV) in healthy overweight and slightly obese men and women?

Study design

At baseline, all participants have to attend the research facilities to perform the measurements. Before the test day, a fasting blood sample will be drawn, 24-hour ambulatory BP measurements will be performed and 24-hour urine will be collected.

After the first test day (baseline (BL) measurement), the overweight and slightly obese participants will be randomly assigned to receive magnesium citrate or a placebo for 24 weeks. During this period, subjects will visit our research facilities every 4 weeks to receive new supplies. After 12 and 24 weeks (follow-up (FU) measurements), measurements will be repeated.

Intervention

After the first test day, the overweight and slightly obese subjects will be randomly assigned to receive magnesium citrate or a placebo for 24 weeks.

Subjects assigned to the oral magnesium treatment will be instructed to take one capsule thrice daily that contains magnesium citrate (total daily dose: 350 mg elemental magnesium) at breakfast, lunch and dinner for 24 weeks. Magnesium citrate will be administered because of its superior bioavailability over other formulations.

Subjects assigned to the placebo treatment will undergo the same tests, but will be instructed to take one capsule thrice daily that contains placebo (identical in color, shape, taste and smell to the capsules containing magnesium citrate) for 24 weeks.

Study burden and risks

Before the start of the study, subjects will attend the research facilities for a screening visit. During this visit, anthropometric measurements (weight, length, body mass index) will be performed and BP will be determined. Dietary magnesium intake will be assessed using a questionnaire. In addition, a venous blood sample will be drawn for analysis of serum total cholesterol and triacylglycerol concentrations, and plasma glucose concentrations.

Following screening (30 minutes), all participants will visit our research facilities at the MRUM for 120 minutes (BL measurements). Before the test day, a fasting blood sample will be drawn (20 minutes), 24-hour ambulatory BP measurements will be performed and 24-hour urine will be collected. In addition, subjects will visit our research facilities every 4 weeks to receive new supplies. After 12 and 24 weeks, measurements will be repeated (FU measurements). Time investment at 12 and 24 weeks will be 140 minutes. Total time investment for the overweight and slightly obese subjects will be approximately 540 minutes (9 hours).

The amount of blood drawn will be 219 mL (9.0 mL during the screening visit, 35.0 mL before each test day and 35.0 mL at each test day) during the whole study.

No direct health benefit for the participants is expected. Subjects assigned to receive magnesium citrate will consume safe and commercially available products. Only diarrhea, and unspecific mild abdominal and bone pain have been reported after consumption of magnesium supplements. The risks of participation are addressed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Aged between 45-70 years
- Women postmenopausal: two or more years after last menstruation
- BMI between 25-35 kg/m2 (overweight and slightly obese)
- Plasma glucose < 7.0 mmol/L
- Serum total cholesterol < 8.0 mmol/L
- Serum triacylglycerol < 4.5 mmol/L
- No current smoker
- No diabetic patients
- No familial hypercholesterolemia
- No abuse of drugs
- Less than 14 (women) or 21 (men) alcoholic consumptions per week
- Stable body weight (weight gain or loss <3 kg in the past three months)
- No use of proton pump inhibitors or medication known to treat blood pressure, serum lipid or glucose metabolism
- No use of dietary supplements or an investigational product within another biomedical within the previous 1-month
- No severe medical conditions that might interfere with the study, such as epilepsy, asthma, kidney failure or renal insufficiency, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis
- No active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebro vascular accident
- Willingness to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study and during the study
- No difficult venipuncture as evidenced during the screening visit

Exclusion criteria

- High habitual dietary magnesium intake
- Plasma glucose * 7.0 mmol/L
- Serum total cholesterol * 8.0 mmol/L
- Serum triacylglycerol * 4.5 mmol/L
- Current smoker, or smoking cessation <12 months
- Diabetic patients
- Familial hypercholesterolemia
- Abuse of drugs
- More than 14 (women) or 21 (men) alcoholic consumptions per week
- Unstable body weight (weight gain or loss > 3 kg in the past three months)
- Use of proton pump inhibitors or medication known to treat blood pressure, serum lipid or glucose metabolism
- Use of dietary supplements or an investigational product within another biomedical within the previous 1-month
- Severe medical conditions that might interfere with the study, such as epilepsy, asthma, kidney failure or renal insufficiency, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis
- Active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebro vascular accident
- Not willing to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study and during the study
- Not or difficult to venipuncture as evidenced during the screening visit

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2014
Enrollment:	112

Type:	Actual

Ethics review

Approved WMO Date:	27-08-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48784.068.14

Study results

Date completed:	11-09-2015
Actual enrolment:	58