Effect of oral magnesium supplementation on insulin sensitivity and blood pressure in apparently healthy overweight adults: a randomised double-blinded controlled trial

Submission date	Recruitment status	Prospectively registered
27/11/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
18/12/2007	Completed	[X] Results
Last Edited	Condition category	Individual participant data
08/04/2021	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Busan
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602-739

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Effect of oral magnesium supplementation on insulin sensitivity and blood pressure in apparently healthy overweight adults: a randomised double-blinded controlled trial

Study objectives

We analysed whether magnesium supplementation affected insulin sensitivity and Blood Pressure (BP) in apparently healthy Korean subjects as well as in individuals with diabetes and hypertension.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Food Institutional Review Board of Pusan National University Hospital on the 3rd January 2006 (ref: 2006-01).

Study design

Randomised double-blinded controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Overweight, obesity

Interventions

12.3 mmol (300 mg) of elemental magnesium per day in the form of magnesium oxide or placebo. The total duration of treatment and the total duration of follow up are both 12 weeks (i. e., no follow-up).

Intervention Type

Supplement

Phase

Drug/device/biological/vaccine name(s)

Magnesium supplementation

Primary outcome measure

- 1. The HOMeostasis model Assessment of Insulin Resistance (HOMA-IR)
- 2. Quantitative Insulin Sensitivity Check Index (QUICKI)
- 3. Systolic BP
- 4. Diastolic BP

Primary outcomes measured at baseline and 12 weeks (at the end of this study).

Secondary outcome measures

- 1. Lipids
- 2. Serum trace minerals (magnesium, calcium, and phosphorus)

Secondary outcomes measured at baseline and 12 weeks (at the end of this study).

Overall study start date

04/01/2006

Completion date

08/01/2006

Eligibility

Key inclusion criteria

- 1. Aged 30 60 years
- 2. Body mass index greater than or equal to 23 kg/m^2
- 3. Have not taken any supplements or medications, including anti-diabetic drugs, anti-hypertensive drugs, steroids, or hormonal products, during the previous 4 weeks

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

156

Total final enrolment

155

Key exclusion criteria

- 1. Pregnant women
- 2. Those suffering from chronic illnesses, including:
- 2.1. Chronic liver and renal diseases
- 2.2. Severe bradycardia
- 2.3. Myasthenia gravis
- 2.4. Hypermagnesemia

Date of first enrolment

04/01/2006

Date of final enrolment

08/01/2006

Locations

Countries of recruitment

Korea, South

Study participating centre Family Medicine

Busan Korea, South 602-739

Sponsor information

Organisation

TEI (Trace Elements Incorporated) Korea (South Korea)

Sponsor details

Cambridge B/D 2F 1461-15 Seocho-dong Seocho-gu Seoul Korea, South 137-070

Sponsor type

Industry

Website

http://www.teikorea.com

ROR

https://ror.org/00zhe2a05

Funder(s)

Funder type

Industry

Funder Name

TEI (Trace Elements Incorporated) Korea (South Korea)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2009	08/04/2021	Yes	No