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

Submission date
27/11/2007

Recruitment status
No longer recruiting

Registration date
18/12/2007

Overall study status
Completed

Last Edited
08/04/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Not Specified

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