Effect of oral magnesium supplementation on insulin sensitivity in people with type 2 diabetes

Published: 21-09-2021
Last updated: 17-01-2025

To investigate the effect of oral magnesium supplementation on insulin sensitivity in people with T2DM and a low serum magnesium concentration.

Ethical review	Approved WMO
Status	Completed
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON50922

Source
ToetsingOnline

Brief title
Magnesium

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Type 2 diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: via een grant

Intervention

Keyword: Insulin sensitivity, Magnesium supplementation, Type 2 diabetes mellitus

Outcome measures

Primary outcome

The main study parameter is the change in insulin sensitivity after oral magnesium supplementation measured by the mean glucose infusion rate during the last 30 minutes of the hyperinsulinemic euglycemic glucose clamp.

Secondary outcome

Secondary endpoints include the effect of oral magnesium supplementation on HbA1c, insulin dose requirements, symptoms associated with hypomagnesemia, blood pressure, physical activity and glucose-, lipid and inflammatory profile. Additionally, we will explore the differences in glycemic control, lipid profile and blood pressure between people with T2DM and normo- versus hypomagnesemia.

Study description

Background summary

Hypomagnesemia is common in people with type 2 diabetes mellitus (T2DM). Because of its association with insulin resistance, hypomagnesemia has been suggested to play a role in the pathogenesis of T2DM. It is unknown whether magnesium supplementation improves insulin resistance in people with insulin-requiring T2DM and hypomagnesemia.

Study objective

To investigate the effect of oral magnesium supplementation on insulin sensitivity in people with T2DM and a low serum magnesium concentration.

Study design

Placebo controlled, double blinded, randomized controlled, cross-over intervention trial.

Intervention

Participants will receive placebo or magnesium gluconate drink 50 ml three times a day (i.e. total daily magnesium dose of 15 mmol) for six weeks in a randomized cross-over design. After both treatment periods, the participants will undergo a hyperinsulinemic euglycemic glucose clamp.

Study burden and risks

The study participants will not benefit directly from participating in this clinical trial, although theoretically, low magnesium levels are associated with symptoms such as muscle cramps which may decrease during this trial. Magnesium gluconate has a safe profile. Possible side effects of magnesium gluconate are (temporary) gastro-intestinal symptoms like diarrhoea. The use of venous catheters may cause hematomas or phlebitis which are self-limiting. During the clamp there is a potential risk of developing hypoglycemia, yet this risk is very low because plasma glucose levels are frequently monitored and glucose 20% is continuously infused, the rate of which will be increased when glucose levels tend to fall. In over 1000 clamps performed to date, severe hypoglycemia has never occurred.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Clinical diagnosis of type 2 diabetes mellitus
* Treatment with insulin for at least one year
* Minimum age of 18 years
* Ability to provide informed consent

Exclusion criteria

* Treatment with more than 7.5 mg prednisone daily (or a comparable dose of other oral corticosteroids)
* Use of magnesium supplementation in the week before screening
* Any cardiovascular event in the six months before screening
* Illnesses and unstable diseases that interfere with the primary outcome
* Chronic diarrhea
* Alcohol consumption of more than 14 units weekly
* MDRD-GFR < 45 ml/min/1.73m2
* Body-Mass Index < 18 or > 40 kg/m2
* Pregnancy or the wish to become pregnant

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-02-2022
Enrollment:	14
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Magnesium gluconate oral solution
Generic name:	Magnesium gluconate

Ethics review

Approved WMO Date:	21-09-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-12-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-05-2022
Application type:	Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2021-001243-27-NL
CCMO	NL77108.091.21

Study results

Date completed: 15-11-2022

Results posted: 06-11-2023

First publication
03-11-2023