The impact of dietary nitrate ingestion on muscle protein synthesis in elderly type II diabetics

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To investigate whether the in vivo postprandial muscle protein synthetic response is augmented when dietary nitrate ingestion precedes protein ingestion in elderly type 2 diabetics.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37520

Source
ToetsingOnline

Brief title
Pro-Nitrate

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
adult onset diabetes, Type 2 diabetes

Health condition

spiermassametabolisme

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diabetes, Muscle, Nitrate, Protein

Outcome measures

Primary outcome

Muscle protein synthetic rate, expressed as fractional synthetic rate (FSR).

Secondary outcome

Rate of protein digestion and absorption and whole body protein balance.

Study description

Background summary

In general, aging is associated with the development of sarcopenia; a gradual, yet progressive, age-related loss of skeletal muscle mass and strength leading to impairment in muscle function, disability and a loss of independence. This reduction in muscle quality, in combination with changes to muscle metabolic regulation, increase the overall risk of developing chronic metabolic disease such as type II diabetes. Sarcopenia is assumed to be related to the impaired muscle protein synthetic response to protein and/or amino acid administration in the elderly compared with the young. This attenuated response may be a consequence of the blunted insulin-stimulated increase in endothelial-dependent-nitric oxide (NO) vasodilation, potentially limiting amino acid perfusion and subsequent protein synthesis. As such, any insulin-dependent action is further compromised in elderly individuals living with type 2 diabetes. Not surprisingly, these individuals commonly experience a dysregulation of NO metabolism because of the hampered insulin-activated NO synthase (NOS). Interestingly, numerous reports have linked a diet high in nitrate (from leafy green vegetables) with a decrease in the prevalence of type 2 diabetes. Nitrate supplementation may possess the ability to improve NO metabolism independent of insulin through the NO3-NO2-NO pathway. Any improvement in NO-mediated vasodilation may increase amino acid perfusion leading to increased postprandial muscle protein synthesis. However, no study has tested the impact of nitrate ingestion on postprandial muscle protein

synthesis in elderly type 2 diabetics.

Study objective

To investigate whether the in vivo postprandial muscle protein synthetic response is augmented when dietary nitrate ingestion precedes protein ingestion in elderly type 2 diabetics.

Study design

Double-blind, parallel-design, placebo controlled study.

Intervention

1 bolus ingestion of sodium nitrate (NaNO3-) (0.1 mmol NO3- /kg body weight) or an equalmolar amount of sodium chloride (NaCl) (placebo) dissolved in water and ingested 2.5 h prior to the ingestion of 20 g of intrinsically labelled casein protein.

Study burden and risks

The risks involved in participating in this experiment are minimal. Insertion of the catheters in a vein is comparable to a normal blood draw and the only risk is a small local hematoma. This is also true for muscle biopsies. Muscle biopsies will be taken through a small (5 mm) incision, following local anesthetics of the skin and muscle fascia, and will heal completely. Muscle biopsies will only be obtained by an experienced physician. The test beverages contain intrinsically labeled dietary protein which is safe for human consumption and have been used in previous studies (MEC 06-3-064, MEC 07-3-086, MEC 09-3-078.3). The labeled, non-radioactive amino acids tracers that will be infused intravenously are produced according to GMP standards and are safe for human use. The sodium nitrate has no side effects and specifically produced for human consumption.

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

- Male
- 65-85 y
- Diabetes type II

Exclusion criteria

- Smoking
- Insulin use
- Obesity (BMI > 30 kg/m2)
- Hypertension
- All comorbidities interacting with mobility and muscle metabolism
- use of anticoagulants and gastric acid inhibitors, blood disease and allergy for lidicaine
- blood donation in last 3 months

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2012
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	28-10-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-02-2012
Application type:	Amendment
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	NL37850.068.11