The impact of dietary nitrate supplementation on exercise-induced cardiac troponin T release in type 2 diabetic patients: a pilot-study

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To assess whether dietary nitrate supplementation blunts the ischemia-reperfusion-induced rise in cTnT levels following exercise in type 2 diabetic patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON37028

Source
ToetsingOnline

Brief title
Dietary nitrate and cardiac troponin T

Condition

- Coronary artery disorders
- Diabetic complications
- Diabetic complications

Synonym
exercise-induced cTnT release, exercise-induced heart damage

Research involving
Human

Sponsors and support

Primary sponsor: Human Movement Sciences
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dietary nitrate, ischemia-reperfusion, nitric oxide, type 2 diabetes

Outcome measures

Primary outcome

cTnT levels at baseline and over the subsequent 6 h period following exercise

Secondary outcome

Plasma nitrate and plasma nitrite concentrations

Blood pressure measured at 8:00, 9:30, 10:00, 10:30, 11:00, 12:15, 14:00 and

16:00 h.

Orthogonal polarization spectroscopy (OPS) will be applied at 8:00, 10:00,

11:00 and 13:30 and 16:00 h. This non-invasive method has proven to quantify

microvascular flow and endothelium permeability for erythrocytes in the oral

cavity.

Study description

Background summary

Blood cardiac troponin T (cTnT) concentration is a widely used marker of acute cardiac injury. Previous research has shown that several type 2 diabetic patients show large increments in cTnT levels over the subsequent hours following a single bout of moderate-intensity endurance-type exercise. This phenomenon is likely attributed to cardiac ischemia-reperfusion injury caused by reduced nitric oxide (NO) bioavailability. Recent evidence indicates that ingestion of dietary nitrates dramatically increases the bioavailability of NO, and as such, may be protective against cardiac ischemia-reperfusion injury.

Study objective

To assess whether dietary nitrate supplementation blunts the ischemia-reperfusion-induced rise in cTnT levels following exercise in type 2 diabetic patients.

Study design

The study is a double-blind, placebo-controlled, randomized cross-over trial.

Intervention

After an initial screening, subjects will be randomly assigned to a test day during which they receive a sodium nitrate (test supplement) or sodium chloride (placebo) supplement. During each test day, subjects will ingest the dietary nitrate or placebo supplement at 8:00 h and perform a single session of moderate-intensity cycling exercise 2 hours later. Sixty minutes of moderate-intensity endurance-type exercise will be performed at 50% Wmax. Blood samples will be collected at baseline and over the 6 hour period following exercise. After a wash-out period of at least 2 weeks, the intervention period will be repeated with either the placebo or sodium nitrate supplement.

Study burden and risks

With the results of this study we hope to gain novel insight in the role of NO bioavailability in ischemia-reperfusion induced cardiac injury in type 2 diabetic patients. Because candidate subjects participated in a recent study (MEC 09-3-028; substudy E), cardiac function has been monitored by an ECG within the last year. Subjects with severe cardiac abnormalities were excluded for participation in that study. As such, only subjects without major cardiac abnormalities are candidate to participate in the present study.

The exercise session will be performed at moderate-intensity (50% Wmax), and has proven feasible in type 2 diabetic patients. In our previous studies (MEC 09-3-028) (20, 21) no adverse events occurred during or following exercise at the same duration and intensity. In the present study, exercise will be performed 1.5 h following breakfast and subjects receive lunch 1.5 h following exercise. As such, the risk for exercise-induced hypoglycaemia is minimal. However, in case subjects show hypoglycaemic symptoms, capillary glucose concentrations will be measured with a finger prick and subjects receive dextrose tablets when necessary.

The sodium nitrate and sodium chloride are human grade and do not pose any health risk at the level administered. No known complications (besides a mild headache) from a bolus ingestion of sodium nitrate have been reported.

At the insertion site of the intravenous catheter, a hematoma could occur.

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

-type 2 diabetes
-exercise-induced rise in cardiac troponin T (>3 ng/L)

Exclusion criteria

-HbA1c <6.0% or >10.0%
-diagnosed impaired renal or liver function

-morbid obesity (BMI>35 kg/m2)
-incident cardiovascular events in the last year (heart attack, stroke, aneurysms)
-treatment with medication which contain nitrates and/or having vasodilatory effects

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2012
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-09-2012
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	NL41071.068.12