

THE EFFECT OF DIETARY NITRATE AND SUCROSE ON GI FUNCTION DURING EXERCISE

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The aim of this study is to investigate the effects of both dietary nitrate and sucrose ingestion on splanchnic perfusion and intestinal (enterocyte) damage during high intensity exercise.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43091

Source

ToetsingOnline

Brief title

Nitrate and sucrose: GI function

Condition

- Other condition

Synonym

intestinal blood flow, intestinal damage

Health condition

GI function (intestinal damage and blood flow) during exercise

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: NWO (STW)

Intervention

Keyword: exercise, GI function, nitrate, sucrose

Outcome measures

Primary outcome

Intestinal damage: plasma intestinal fatty acid binding protein (I-FABP)

Secondary outcome

GI perfusion: gastric tonometry

Plasma nitrate and nitrite

Plasma glucose

Resting blood pressure

Study description

Background summary

The gastrointestinal (GI) tract plays an important role in the human body. The GI wall regulates the uptake of nutrients, and also has a very important function as a barrier between the internal and external environment. The penetration of harmful substances and microbiota from the GI lumen (external environment) into the systemic circulation (internal environment) depends on this barrier.

During high-intensity exercise, GI complaints and intestinal injury frequently occur, thereby hampering exercise performance. Splanchnic hypoperfusion, resulting in intestinal damage, has been postulated as one of the key underlying mechanisms for exercise associated GI symptoms. Attenuating such hypoperfusion therefore appears a promising strategy to reduce GI injury and its negative effects on performance. During episodes of splanchnic hypoperfusion, the synthesis of nitric oxide (NO) is suppressed. A previous study of our group found that supplementation with L-citrulline as a donor of the endogenous NOS dependent pathway lead to improved splanchnic blood flow and

reduced intestinal damage during high intensity exercise. By acting as a local NO donor, through the nitrate-nitrite-NO pathway, dietary nitrate may also increase microcirculatory blood flow in the splanchnic area. Next to NO, macronutrients can also act as potential GI stimulators. The ingestion of carbohydrates will directly stimulate an increase in splanchnic microcirculatory blood flow, simply through the normal digestive processes taking place. Thus, both ingestion of nitrate and carbohydrates may effectively reduce intestinal damage, and as such prove valuable in reducing the negative effects of exercise on the gut.

Study objective

The aim of this study is to investigate the effects of both dietary nitrate and sucrose ingestion on splanchnic perfusion and intestinal (enterocyte) damage during high intensity exercise.

Study design

In a randomized, placebo-controlled, cross-over design, male cyclists will perform 1 h of high-intensity exercise after the ingestion of: 1) a water placebo (PLA), 2) a sodium nitrate drink (NIT), 3) a sucrose solution (SUC). Splanchnic perfusion and enterocyte damage will be monitored during and up to 1 h after the exercise sessions.

Intervention

On each test day the participants will perform 60 min of cycling at 70% W_{max}, where the effect of each intervention on GI parameters will be investigated.

NIT: 1.1 g of NaNO₃ (sodium nitrate) dissolved in 200 mL water 2.5 h prior to exercise. 200 mL water provided both 15 min prior and 30 min into exercise.

SUC: 1.1 g of NaCl (placebo) dissolved in 200 mL water 2.5 h prior to exercise. 20 g sucrose dissolved in 200 mL water provided both 15 min prior and 30 min into exercise.

PLA: 1.1 g of NaCl (placebo) dissolved in 200 mL water 2.5 h prior to exercise. 200 mL water provided both 15 min prior and 30 min into exercise.

Study burden and risks

The risks involved in participating in this experiment are low. The insertion of the nasogastric tonometry catheter is performed by a certified physician and is a standard medical procedure (e.g. for enteral feeding). The insertion can feel somewhat unpleasant, but is of very low risk. Some subjects experience the urge to vomit. There is minor risk for complications (e.g. nose bleed, sinusitis and transient sore throat); given the short time frame for which the catheter is maintained in situ (i.e., 180 minutes), these risks are minimal. The procedures have previously been safely applied and their risks are also

described in MEC09-3-005 and MEC10-3-064. Insertion of a catheter on the hand is comparable to a normal blood draw and the only risk is a small hematoma. The subjects will cycle for 60 min at 70% Wmax. This exercise protocol can lead to tiredness in the hours after cycling and muscle soreness up to 1-2 days after cycling. The same protocol has been applied in MEC09-3-005 and MEC10-3-064.

The administered dose of nitrate has been used in multiple clinical and exercise studies and is previously approved by the METC (e.g. MEC13-3-059). The most commonly reported side effect is mild gastrointestinal distress (bloating, belching), and occasional reports of mild headache (which may or may not be associated with the nitrate). The long-term effects of nitrate ingestion still need to be fully investigated. All supplements are produced according to GMP standards and are safe for human use.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Healthy (see exclusion criteria below)
- 18 - 40 years of age
- $18.5 < \text{BMI} < 30 \text{ kg/m}^2$
- Engagement in regular cycling activity (at least 2x per wk)
- $W_{\text{max}} > 4.5 \text{ W/kg}$

Exclusion criteria

- Diagnosed or on medication for: Cardiovascular disease; Chronic Obstructive Pulmonary Disease (COPD); Rheumatoid arthritis (RA); Inflammatory bowel disease (IBD); Morbus Crohn and colitis ulcerosa; Irritable bowel syndrome; Inflammatory systemical diseases; Diabetes Mellitus; Diabetes Insipidus; Hypo- or hyperthyreoidism; Kidney failure; Donation of blood within the last 3 months; Cancer, Alcohol use of > 5 units per day; Drugs abuse; Use of regular medication; Oversensitive for sucrose; Phenol Keton Uria (PKU); Acute porphyria in the past.
- Smoking
- Currently supplementing diet with nitrate

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	17-01-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date: 21-12-2016

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	NL59697.068.16

Study results

Date completed: 11-05-2017

Actual enrolment: 16

Summary results

Trial is ongoing in other countries