Dietary advice focused on increasing dietary nitrate intake in active individuals

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON43059

Source
ToetsingOnline

Brief title
Nitrate: vegetables as a dietary source

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
blood pressure, Pharmacokinetics

Research involving
Human

Sponsors and support

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

Intervention

Keyword: nitrate, vegetables

Outcome measures

Primary outcome

The primary parameter will be the increase in plasma nitrate concentrations

from baseline fasting levels (which will be measured at 3h post-ingestion on

day 1, 4, and 7 of the intervention)

Secondary outcome

Secondary parameters:

- plasma nitrite concentrations

- salivary nitrate and nitrite concentrations

- blood pressure

- urinary nitrosamines

- dietary intake

Study description

Background summary

Recent research has shown that intake of nitrate (NO3) can lead to an increase in plasma nitrite and nitrate levels, and a reduction in blood pressure at rest and pulmonary oxygen uptake during exercise. These effects are related to the endogenous production of nitric oxide (NO), which is associated with a rise in plasma nitrite levels.

The consumption of vegetables declared for 60-80% of the daily intake of nitrate. So far, most studies mainly using sodium nitrate (NaNO3) and red beet juice to induce these metabolic effects. A recent study from our group shows that acute supplementation of nitrate-rich vegetables can provide the same

effects as sodium nitrate and red beet juice on the rise in plasma nitrite and nitrate values **and a reduction in blood pressure. However, there is yet no knowledge whether prolonged intake of nitrate via the usual diet can show the same effects. In addition, it is not known whether taking those quantities of vegetables are practicable.

Based on the gaps in current literature, our main goal will therefore be to gain further insight into the effect of 7 days supplementation with concentrated nitrate-rich beet juice compared with dietary advice aimed at increasing the nitrate intake through the habitual diet.

Study objective

The aim of the current study is to compare the effects of supplementation with concentrated nitrate-rich beetroot juice versus dietary advice to increase dietary nitrate intake through the habitual diet. Therefore, we will assess the impact of 1-wk concentrated beetroot juice supplementation vs 1-wk of dietary advice to increase vegetables consumption on plasma and saliva nitrate and nitrite concentrations, blood pressure, urinary nitrosamine formation, and dietary nitrate intake.

Study design

Randomized, crossover intervention study

Intervention

Participants will receive 1-wk of dietary guidance in which they will be provided with a sufficient amount of vegetables, representing 400 mg (6.5 mmol) nitrate per serving (i.e. each day), including information about nitrate and nitrate rich recipes. In a randomized cross-over manner, participants will also follow a 1-wk supplementation protocol in which they will ingest 400 mg (6.5 mmol) nitrate per day in the form of concentrated red beetroot juice. Both trials will be separated by a 1-wk washout period.

Study burden and risks

Participants will be required to report to the laboratory for a total of 11 visits for a total of maximally 15 hours, including a screening session. Prior to the first experimental visit, participants will be asked to record their diet for 7 days and refrain from strenuous physical exercise or labour for the 24h preceding the visit. Participants will be asked to avoid caffeine and alcohol for 12h and 24h preceding each visit, respectively.

They will be asked to refrain from exercise for the 24h prior to subsequent visits. In total, participants will donate ten blood samples, representing ~7.5

mL over the course of 4 weeks. Insertion of the needle for blood sampling could result in a small hematoma. Participants also have to perform three 24h urine collections. In addition, the main time commitment will consist of filling in three 7-day food diaries.
The administered dose of nitrate in beetroot juice has been used in multiple clinical and exercise studies and is a commercially available supplement. The most commonly reported side effect is beeturia (red-coloured urine/faeces, 15-20% of the population) and mild gastrointestinal distress (bloating, belching), and occasional reports of mild headache (which may or may not be associated with the nitrate). The vegetables used in the present study are freely available natural products. The only comparison available is from the ingestion of nitrate-rich beverages, which has been described to lead to mild gastrointestinal distress (bloating, belching) in some cases. The long term effects of nitrate ingestion still need to be fully investigated.

There is no direct benefit for the participants, only their contribution to scientific knowledge and the provision of vegetables.

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

- Healthy (not being diagnosed with a cardiovascular or metabolic disease and/or no presence of mental/psychological conditions)
- 18 - 45 years of age
- 18.5 < BMI < 30 kg/m2
- Engagement in regular physical activity (> 2 h/week) ;(page 18, protocol)

Exclusion criteria

- Use of medication
- Smoking
- Currently supplementing diet with nitrate;(page 18, protocol)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO
Date: 02-11-2016

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

ID: 25661
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58765.068.16
Other	Registratie volgt na goedkeuring protocol
OMON	NL-OMON25661

Study results

Date completed: 01-09-2017

Actual enrolment: 30

Summary results
Trial is onging in other countries