

The effect of concentrated beetroot juice with or without vitamin C on the levels of N-nitroso compounds in urine

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The main aim of the study will be to compare the urinary N-nitroso compounds levels after intake of 70 ml of concentrated red beetroot juice containing 400 mg nitrate either with or without supplementation with 1 g vitamin C.

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

Summary

ID

NL-OMON43980

Source

ToetsingOnline

Brief title

NOC's after consumption of beetroot juice with or without vitamin C

Condition

- Other condition

Synonym

not applicable

Health condition

gericht op preventie van vorming van mogelijk kankerverwekkende stoffen

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: beetroot juice, N-nitroso compounds, prevention, vitamin C

Outcome measures

Primary outcome

The primary study parameter is the total NOC concentration in the urine of the participants.

Secondary outcome

The secondary study parameters are urine nitrate and nitrite concentration.

Study description

Background summary

The interest in consumption of nitrate-rich red beetroot juice has increased greatly over the last couple of years. Beetroot juice contributes to the formation of endogenous nitric oxide, causing a number of beneficial effects. However, since beetroot juice is very rich in nitrate, consuming this product may also cause endogenous formation of N-nitroso compounds, which are considered to be carcinogenic. Furthermore, we will examine what the effect is of supplementation with vitamin C on the endogenous formation of N-nitroso compounds. Studies show that vitamin C can decrease the formation of these compounds, which could potentially mean that consuming beetroot juice in combination with vitamin C would diminish potential negative side effects of this consumption.

Study objective

The main aim of the study will be to compare the urinary N-nitroso compounds levels after intake of 70 ml of concentrated red beetroot juice containing 400 mg nitrate either with or without supplementation with 1 g vitamin C.

Study design

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The participants will be randomized equally to the groups. Half of the study population will orally consume red beetroot juice without vitamin C for a single week. The other half of the study population will orally consume red beetroot juice in combination with vitamin C for a single week.

Intervention

Beetroot-juice will be consumed by both groups. However, the intervention group will also consume vitamin C in addition.

Study burden and risks

The consumption of beetroot-juice can cause gastro-intestinal distress on the short-term. Thereby, it can cause beeturia (red colouring of urine) and a headache. Exposure to beetroot-juice during a longer period of time, can increase the risk on cancer due to the formation of N-nitroso compounds. However, in this study participants will only consume beetroot-juice during a relatively short period of time.

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

18-45 years of age

$18,5 < \text{BMI} < 30 \text{ kg/m}^2$

Regular physical activity (minimum of 1 hour and maximum of 8 hours a week)

Exclusion criteria

Use of medication

Smoking

Currently supplementing diet with vitamin C

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date: 04-04-2016

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: 24315

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL55247.068.15
OMON	NL-OMON24315