EFFECT OF INCREASING DIETARY NITRATE INTAKE BY DIETARY INTERVENTION ON BLOOD PRESSURE IN (PRE)HYPERTENSIVE MEN AND WOMEN

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21682

Source Nationaal Trial Register

Brief title Heart Beet

Health condition

hypertention

Sponsors and support

Primary sponsor: -Source(s) of monetary or material Support: eat2move

Intervention

Outcome measures

Primary outcome

24h blood pressure

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Secondary outcome

- Plasma concentrations: plasma nitrate and nitrate, plasma cholesterol, HDL, LDL, triglyceride, troponin I;

- Dietary intake: total macro- and micronutrient intake, vegetable and dietary nitrate intake;
- Blood pressure and heart rate at rest, during submaximal exercise and orthostatic resonse
- Exhaled nitric oxide;

Study description

Background summary

Rationale: Green leafy vegetables (e.g., spinach, rocket salad/arugula, lettuce) and beetroot share the common characteristic of high nitrate content. Recently, there has been an increased interest in the role of dietary nitrate as a biologically active nitric oxide (NO) donor, due to its proposed beneficial effects on cardiovascular health. Therefore, food based ways of increasing nitrate intake through the diet appear to form a worthwhile strategy to induce cardio protective effects. However, there is a lack of knowledge on the effects of a prolonged elevation of nitrate intake via the habitual diet.

Objective: The main aim of the current study is to investigate the effect of a 12 week dietary intervention focusing on increasing dietary nitrate intake on 24h blood pressure. Besides, we want to investigate the effects on:

- Plasma concentrations: plasma nitrate and nitrate, plasma cholesterol, HDL, LDL, triglyceride, troponin I;

- Dietary intake: total macro- and micronutrient intake, vegetable and dietary nitrate intake;
- Blood pressure and heart rate at rest, during submaximal exercise and orthostatic resonse - Exhaled nitric oxide;

Study design: The present study will use a randomized, controlled, parallel study design Study population: 87 (pre)hypertensive males and females, registered to participate in the Nijmegen Four Days Marches 2019.

Intervention: 12 weeks of educational intervention with intense (weekly) personalized monitoring and feedback focusing on nitrate rich vegetables (intervention group), dietary nitrate supplementation (supplementation group) or no intervention (control group). Main study parameters/endpoints: The primary outcome is the change in 24h blood pressure

after 12 weeks intervention, which will be compared between the intervention,

supplementation and control group. Furthermore, blood pressure and heart rate responses during exercise and orthostasis will be assessed before, after 12 weeks and during the Four Days Marches.

Study objective

Study design

before and after

Intervention

dietary counseling focussing on nitrate rich vegetables, beetrootjuice supplementation and control

Contacts

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Eligibility criteria

Inclusion criteria

- Prehypertension or hypertension:

Prehypertension is a systolic and/or diastolic pressure above 131/86 – 139/89 mmHg. Hypertension is a systolic and/or diastolic pressure above 140/90mmHg [22]. When one of the two is equal to or higher than 131-86, the participant will be included.

- Current vegetable intake <200 g/d based on FFQ;
- Registered for the Nijmegen Four Days Marches 2019;
- $-18.5 < BMI \le 35.0 \text{ kg/m2};$
- Able to understand and perform the study procedures.

Exclusion criteria

- Chronic use of medication or products with known vasoactive properties and chronic use of the following products: [63, 64];

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NSAIDs (including acetylsalicylic acid and selective COX-2 inhibitors) sympathomimetics (decongestants, sibutramine, cocaine) Alcohol glycyrretic acid-containing products (including licorice, liquorice and some chewing gums) erythropoietin cyclosporine

timulants ((dex) methylphenidate, (dextroof with) amphetamine, modafinil) some herbs (ephedra, ma huang)

- Currently smoking [23];
- Currently supplementing diet with nitrate.

Study design

Design

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

Recruitment

...

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2019
Enrollment:	87
Туре:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date: Application type:

14-05-2019

First submission

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Study registrations

Followed up by the following (possibly more current) registration

ID: 48183 Bron: ToetsingOnline Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7814
ССМО	NL68764.072.19
OMON	NL-OMON48183

Study results