

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

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

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

Summary

ID

NL-OMON48183

Source

ToetsingOnline

Brief title

Heart Beet

Condition

- Other condition

Synonym

blood pressure, Pharmacokinetics

Health condition

hypertentie

Research involving

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1-05-2025

Human

Sponsors and support

Primary sponsor: Hogeschool van Arnhem en Nijmegen

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

Intervention

Keyword: blood pressure, dietary intervention, dietary nitrate

Outcome measures

Primary outcome

The main aim of the current study is to investigate the effect of a 12 week dietary intervention focusing on increasing vegetable intake on 24h blood pressure.

Secondary outcome

- Plasma concentrations: plasma nitrate and nitrite, plasma cholesterol, HDL, LDL, triglyceride, troponin I;
- Dietary intake: total macro- and micronutrient intake, vegetable and dietary nitrate intake;
- Blood pressure and heart rate
- Submaximal aerobic endurance exercise

Study description

Background summary

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 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 nitrate intake via the habitual diet.

Study objective

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

- Plasma concentrations: plasma nitrate and nitrite, plasma cholesterol, HDL, LDL, triglyceride, troponin I;
- Dietary intake: total macro- and micronutrient intake, vegetable and dietary nitrate intake;
- Blood pressure and heart rate
- Submaximal aerobic endurance exercise

Study design

The present study will use a randomized, controlled, parallel study design

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).

Study burden and risks

For this study participants will be required to report to the research facility for a total of two visits (duration ~60 minutes).

Participants follow a nutritional intervention where they are coached weekly (~60 minutes, every week) to improve their eating behaviour or are instructed to use a dietary nitrate supplement daily. During the study period, participants have to fill in a dietary record (three total, ~60 minutes per recall). Participants are asked to refrain from strenuous physical exercise or labour for the 24 h preceding the test days. In addition, participants will be asked to avoid caffeine and alcohol for 12 and 24 h preceding each visit. They will be asked to refrain from using any antibacterial mouthwash/toothpaste, and tongue-scraping throughout the course of the study (as this interferes with the conversion of nitrate to nitrite in the oral cavity). A venepuncture will be performed for blood sample collection during each test day. Withdrawal of a venous blood sample is associated with a 5% risk of developing a haemorrhage, but will fully disappear within 2 weeks and is not associated with any (functional) limitations. The repeated blood pressure measurements during a 24-h recording are known to cause some discomfort when the cuff is inflated to

a suprasystolic pressure, and requires participants to remain still during the measurement. This is also the case during the lab-based blood pressure measurements. The advised daily intake of (nitrate rich) vegetables in the current study has been administered in multiple intervention studies. No adverse events were reported, except for mild gastrointestinal distress (bloating, belching) in a few cases.

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

- Elevated blood pressure or stage 1 hypertension:

Elevated blood pressure. Elevated blood pressure is a systolic pressure ranging from 120 to 129 mm Hg and a diastolic pressure below 80 mm Hg. Elevated blood pressure tends to get worse over time unless steps are taken to control blood pressure.

Stage 1 hypertension. Stage 1 hypertension is a systolic pressure ranging from 130 to 139 mm Hg or a diastolic pressure ranging from 80 to 89 mm Hg.

- Current vegetable intake <200 g/d based on FFQ;
- Registered for the Nijmegen Four Days Marches 2019;
- $18.5 < \text{BMI} \leq 35.0 \text{ kg/m}^2$;
- Able to understand and perform the study procedures.

Exclusion criteria

- Use of medication (with known vasoactive properties);
- Currently smoking
- Currently supplementing diet with nitrate.

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):	01-04-2019
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO	
Date:	14-03-2019
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen

(Wijchen)

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: 21682

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL68764.072.19
Other	Onderzoek is aangemeld, ik wacht op een NCT nummer
OMON	NL-OMON21682

Study results

Date completed: 01-09-2019

Actual enrolment: 81

Summary results

Trial is ongoing in other countries