

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

Gepubliceerd: 14-05-2019 Laatst bijgewerkt: 19-03-2025

| | |
|-----------------------------|-----------------------|
| Ethische beoordeling | Positief advies |
| Status | Werving gestopt |
| Type aandoening | - |
| Onderzoekstype | Interventie onderzoek |

Samenvatting

ID

NL-OMON21682

Bron

Nationaal Trial Register

Verkorte titel

Heart Beet

Aandoening

hypertension

Ondersteuning

Primaire sponsor: -

Overige ondersteuning: eat2move

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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 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 at rest, during submaximal exercise and orthostatic response
- 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.

Doel van het onderzoek

-

Onderzoeksopzet

before and after

Onderzoeksproduct en/of interventie

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

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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;
- $18.5 < \text{BMI} \leq 35.0 \text{ kg/m}^2$;
- Able to understand and perform the study procedures.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Chronic use of medication or products with known vasoactive properties and chronic use of the following products: [63, 64];
NSAIDs (including acetylsalicylic acid and selective COX-2 inhibitors)
sympathomimetics (decongestants, sibutramine, cocaine)

Alcohol
glycyrrhetic acid-containing products (including licorice, liquorice and some chewing gums)
erythropoietin
cyclosporine
stimulants ((dex) methylphenidate, (dextrofetamfetamine) amphetamine, modafinil)
some herbs (ephedra, ma huang)
- Currently smoking [23];
- Currently supplementing diet with nitrate.

Onderzoeksopzet

Opzet

| | |
|------------------|-------------------------|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blinding: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

Deelname

| | |
|-------------------------|-----------------------|
| Nederland | |
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-05-2019 |
| Aantal proefpersonen: | 87 |
| Type: | Werkelijke startdatum |

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

| | |
|-----------------|------------------|
| Positief advies | |
| Datum: | 14-05-2019 |
| Soort: | Eerste indiening |

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48183

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten