DIETARY NITRATE INTAKE IN PATIENTS WITH PERIPHERAL ARTERIAL DISEASE

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Investigate the acute effect of beetroot juice (BRJ) and high nitrate vegetables (HNV) vs. nitrate depleted beetroot juice (placebo (PL)) on exercise tolerance and vascular function in participants with diagnosed peripheral arterial disease.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON26302

Bron
NTR

Verkorte titel
Walk-ON

Aandoening

claudicatio, peripheral arterial disease, etalagebenen

Ondersteuning

Primaire sponsor: Eat2Move
Overige ondersteuning: Eat2Move

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

maximal walking distance

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Dietary nitrate supplementation has been associated with several cardiovascular benefits such as a reduction in blood pressure [1, 2] and improved revascularization in chronic ischemia [3]. Whilst dietary nitrate has ergogenic effects in healthy individuals, these earlier findings of the benefits of dietary nitrate suggests that ergogenic effects may also apply to clinical settings, e.g., patients with peripheral arterial disease [4]. Yet, there is still very limited evidence in this patient population. Furthermore, the majority of studies has used beetroot juice as the nitrate carrier and it is unknown whether potential benefits could also be induced through other strategies such as increasing habitual nitrate intake through the diet.

Objective: The aim of the current study is to:

Investigate the acute effect of beetroot juice (BRJ) and high nitrate vegetables (HNV) vs. nitrate depleted beetroot juice (placebo (PL)) on exercise tolerance and vascular function in participants with diagnosed peripheral arterial disease.

Study design: randomized cross-over intervention study

Study population: 18 patients diagnosed with PAD.

Intervention: In a randomized cross-over manner, participants will follow an acute supplementation protocol in which they will eat a high nitrate meal in de form of vegetables and/or ingest 400 mg (6.5 mmol) nitrate in the form of concentrated red beetroot juice and/or placebo.
Main study parameters/endpoints: The primary parameter will be exercise tolerance. Vascular function will be determined throughout the trials as secondary parameters. Tertiary parameters will be plasma nitrate and nitrite and dietary intake.

Doel van het onderzoek

Investigate the acute effect of beetroot juice (BRJ) and high nitrate vegetables (HNV) vs. nitrate depleted beetroot juice (placebo (PL)) on exercise tolerance and vascular function in participants with diagnosed peripheral arterial disease.

Onderzoeksopzet

-

Onderzoeksproduct en/of interventie

- placebo

- beetroot juice

- nitrate-rich vegetables

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- stable intermittent claudication for at least three month;

- ABI (the ratio of BP in the lower legs to the BP in the arms) <0.9 and/or an ABI decreased by more than 0.15 after treadmill testing regardless of their ABI at rest;

- Rutherford classification for chronic limb ischemia 1-4 and/or Fontaine classification stage IIA, IIB or III

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

A potential participant who meets any of the following criteria will be excluded from participation in this study:

- any condition other than PAD that limits walking;

- patients diagnosed with chronic kidney disease and/or or patients with insulin dependent diabetes;

- previous endovascular or surgical treatment for claudication within the last 12 months;

- individuals with critical limb ischemia, who are wheel-chair bound, or who have an above or below-knee amputation;

- using dietary nitrate supplements;

- using isosorbide dinitrate/mononitrate and/or contraindicated sildenafil, tadalafil, vardenafil .

Onderzoeksopzet

Opzet

Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd

Controle: Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-06-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46719
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7110
NTR-old	NTR7315
CCMO	NL64448.091.17
OMON	NL-OMON46719

Resultaten