DIETARY NITRATE INTAKE IN PATIENTS WITH PERIPHERAL ARTERIAL DISEASE

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON26302

Source
NTR

Brief title
Walk-ON

Health condition

claudicatio, peripheral arterial disease, etalagebenen

Sponsors and support

Primary sponsor: Eat2Move
Source(s) of monetary or material Support: Eat2Move

Intervention

Outcome measures

Primary outcome

maximal walking distance

Secondary outcome

- PWV

- NIRS

- Dietary intake

Study description

Background summary

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.

Study objective

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

-

Intervention

- placebo

- beetroot juice

- nitrate-rich vegetables

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

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 .

Study design

Design

Intervention model:	Crossover
Allocation:	Randomized controlled trial

Control: Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2018
Enrollment:	18
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-06-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46719
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results