Effect of monomeric and oligomeric flavanols on exercise blood pressure and vascular function in healthy volunteers

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Objective: to evaluate the effects of MOF in comparison to placebo on exercise blood pressure, endothelial function, inflammatory and redox status in healthy volunteers. In addition, the study will aim to assess the impact of MOF supplementation on...

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

Summary

ID

NL-OMON56275

Source
ToetsingOnline

Brief title
Effect of monomeric and oligomeric flavanols on exercise blood pressure

Condition

- Other condition

Synonym
exercise-induced increase in blood pressure, vascular health

Health condition

high normal blood pressure

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: CEP Group Holding B.V.,Industry

Intervention

Keyword: exercise blood pressure, healthy volunteers, monomeric and oligomeric flavanols, vascular function

Outcome measures

Primary outcome

Main study outcomes are changes in systolic blood pressure (SBP) during

submaximal exercise test.

Secondary outcome

• Mean blood pressure (MBP) during submaximal exercise test

• Hemodynamic parameters: SBP, diastolic blood pressure (DBP) and heart rate

(HR) during rest and recovery from submaximal exercise, HR and DBP at

submaximal exercise

• Carotid femoral pulse wave velocity, central aortic BP, augmentation index

• Biomarkers of RAAS activation: angiotensin II, renin, aldosterone

• Biomarkers of inflammation: high-sensitivity C-reactive protein , interleukin

(IL)-6, tumor necrosis factor-alpha

• Biomarkers of oxidative stress: malondialdehyde, trolox equivalent

antioxidant capacity

• Biomarkers of endothelial function: endothelin-1, nitrite/nitrate

• Biomarkers of vascular remodelling: metalloproteinase (MMP)-9, MMP-2, tissue

inhibitor of metalloproteinase (TIMP)-1, TIMP-4.

Study description

Background summary

Exaggerated exercise blood pressure (BP) response in healthy subjects is recognized as a risk factor of hypertension and cardiovascular events. Pathogenetically exaggerated BP response is attributed to compromised vascular(endothelial) functions as well as oxidative stress and inflammation. Monomeric and oligomeric flavanols (MOF) are dietary components with well-characterized beneficial effects on the redox homeostasis, endothelial function and microvascular health. We hypothesize that supplementation with MOF in healthy prehypertensive individuals will modulate vascular function and optimize exercise BP response.

Study objective

Objective: to evaluate the effects of MOF in comparison to placebo on exercise blood pressure, endothelial function, inflammatory and redox status in healthy volunteers. In addition, the study will aim to assess the impact of MOF supplementation on the exercise-induced renin-angiotensin-aldosterone system (RAAS) activation and remodelling of extracellular matrix.

Study design

Single-centre, double-blinded, placebo-controlled, 4 week interventional, cross-over study

Intervention

Subjects will receive 200 mg (two capsules of 100 mg) monomeric and oligomeric flavanols for 28±3 days and 200 mg (two capsules of placebo) for 28±3 days in a randomized sequence. The duration of washout period between two interventions will be 28±3 days.

Study burden and risks

Participation in this study will entail three site visits distributed over a three-month period. During the study research subjects will be asked to undergo two submaximal exercise tests on a bicycle ergometer with monitoring of the BP and heart rate before, during and after the test. In addition, maximal exercise test will be performed in cases when such recent historical test is not available. Participants may encounter a physiological discomfort related to the (sub)maximal exercise loads. The risk of adverse events during (sub)maximal exercise testing in healthy volunteers is regarded as very low. Blood samples will be collected before and after submaximal exercise tests, four times in

total during the study. Medical history, use of medication and food supplements will be assessed by questionnaires. The risk associated with an intake of the investigational product (MOF/placebo) can be regarded as minimal. Only a few AEs, namely mild gastrointestinal discomfort which resolved spontaneously, were reported in subjects participating in previous studies involving use of MOF. Direct benefit for study participants is hard to predict. However, the findings of this trial will help to identify nutritional strategies that might be useful for optimization of exercise BP response and reduction of CV risks in healthy volunteers.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Healthy men and women with normal to high-normal resting blood pressure (systolic blood pressure (SBP) 120 - 139 mm Hg and diastolic blood pressure 80

- 89 mm Hg).
2. Age 35 - 65 years
3. BMI 20 - 32 kg/m^2
4. Hypertensive response to maximal exercise test defined as SBP >= 200 mm Hg (men) and >= 180 mm Hg (women).

Exclusion criteria

1. Active engagement in the weight loss programs, also including slimming diets.
2. Active smoking or abstinence from smoking for less than one year.
3. Use of medications that reduce BP and/or can potentially influence other study outcomes (ACE-inhibitors, angiotensin receptor blockers, diuretics, painkillers, etc).
4. Intake of polyphenol-containing supplements for two month before and during the whole course of the study.
5. History of diabetes, cardiovascular, respiratory, renal, gastrointestinal, hepatic or other diseases and conditions, which potentially can compromise participation in this study.
6. Intense sporting (>10 h/week) and/or participation in the competition at the professional level.
7. Pregnancy or breastfeeding.
8. Participation in a clinical trial within four weeks prior to inclusion into this study.
9. Vaccination against Covid-19 within two months before the screening/randomization visit or expected vaccination against Covid-19 during the study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-04-2022
Enrollment:	41
Type:	Actual

Ethics review

Approved WMO

Date:	10-09-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04907097
CCMO	NL77344.068.21