Impact of black tea on forearm endothelial function
De invloed van zwarte thee op de vaatfunctie

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25147

Source
NTR

Health condition

Vascular function; endothelial function; black tea; healthy volunteers; blood flow; blood pressure; hypertension
vaatfunctie; zwarte thee; endotheel; gezonde vrijwilligers; bloeddruk; hypertensie

Sponsors and support

Primary sponsor: Department of Physiology, section of Integrative Physiology, Radboudumc Nijmegen
Source(s) of monetary or material Support: Unilever Research & Development Vlaardingen B.V.

Intervention

Outcome measures

Primary outcome

Mean forearm blood flow response (volume change measured by venous occlusion plethysmography) to intra-arterially administered acetylcholine (i.e. endothelium-independent vasodilation)

Secondary outcome

Mean forearm blood flow response (volume change measured by venous occlusion plethysmography) to intra-arterially administered sodium nitroprusside (i.e. endothelium-dependent vasodilation);
Mean forearm blood flow response (volume change measured by venous occlusion plethysmography) to intra-arterially administered sodium L-NMMA(i.e. nitric oxide-blocker; endothelium-dependent vasoconstriction)

Study description

Background summary

Previous research showed that, even small amounts of, black tea lowers blood pressure in healthy people and people with hypertension.
In this study, we will investigate the effects of acute ingestion of black tea to endothelial function by venous occlusion plethysmography in healthy volunteers. We will study the mechanism underlying the blood pressure lowering effects of black tea.

Voorgaand onderzoek heeft laten zien dat zwarte thee de bloeddruk verlaagd, zowel bij gezonden mensen als mensen met een verhoogde bloeddruk. In deze studie willen we de acute effecten van het drinken van zwarte thee onderzoeken met veneuze occlusie plethysmografie bij gezonde vrijwilligers. Op deze manier onderzoeken we het mechanisme dat ter grondslag ligt aan de bloeddrukverlagende effecten van zwarte thee.

Study objective

We hypothesize that black tea ingestion (approximately 530 mg tea polyphenols) in healthy middle-aged humans will lead to a larger mean forearm blood flow response to acetylcholine (i.e. endothelium-dependent vasodilation)
We hypothesize that black tea ingestion (approximately 530 mg tea polyphenols) in healthy middle-aged humans will not change mean forearm blood flow response to sodium nitroprusside (i.e. endothelium-independent vasodilation)
We hypothesize that black tea ingestion (approximately 530 mg tea polyphenols) in healthy middle-aged humans will lead to a larger decline in mean forearm blood flow response to L-NMMA (i.e. nitric oxide-blocker; endothelium-dependent vasoconstriction)

Study design

not applicable; cross-over design

Intervention

ingestion of black tea vs placebo-tea

Contacts

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Eligibility criteria

Inclusion criteria

Healthy subjects:
- Males and post-menopausal (> 1 years) females
- Aged >45 and < 75 years
- Body mass index (BMI) between 18.0 and „T35.0 kg

Exclusion criteria

- Regular performance of strenuous exercise/sport of > 2 hours per week
- Current smoker or has stopped smoking less than 6 months before start of study
- Self reported alcohol intake of >21 units/week)
- Established cardiovascular disease
- Diabetes mellitus
- Blood pressure > 160/100 mmHg
- Subjects taking any medication that might affect endothelial function (e.g. but not limited to beta-blockers, ACE-inhibitors, statins, anti-coagulants, anti-depressants, hormone replacement therapy) will be excluded from the study. Subjects who are on stable medication for which there is no indication of an effect on endothelial function, will be allowed to

participate.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-12-2014
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion

Date:	17-12-2014
Application type:	First submission

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
NTR-new	NL4789
NTR-old	NTR4929
Other	: CMO 2014-1264

Study results