The effect of lower body negative pressure on cerebral autoregulation in young and elderly healthy volunteers

Published: 29-05-2009
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The aim of the present study is to investigate cerebral vasoreactivity in response to lower body negative pressure in young and elderly healthy men, as a measure of cerebral autoregulatory responsiveness.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON33320

Source
ToetsingOnline

Brief title
ELOCA study

Condition

- Structural brain disorders
- Decreased and nonspecific blood pressure disorders and shock

Synonym
orthostasis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: blood pressure, cerebral autoregulation, lower body negative pressure

Outcome measures

Primary outcome

Change in (regional) cerebral blood flow and cerebral blood volume.

Secondary outcome

Cerebral blood flow velocity of main feeding cerebral arteries, continuous

blood pressure and heart frequency.

Study description

Background summary

Although hypertension in midlife is associated with an increased risk of dementia in late- life, in late-life cognitive impairment is associated with lower blood pressures. Possibly, higher blood pressures are needed to maintain an adequate brain perfusion with a possible increasing failure of cerebral autoregulation with increasing age.

Study objective

The aim of the present study is to investigate cerebral vasoreactivity in response to lower body negative pressure in young and elderly healthy men, as a measure of cerebral autoregulatory responsiveness.

Study design

Intervention study with intra-individual paired measurements for measuring the effect of intervention and case-control design for the comparison between the effect in young and older study subjects.

Intervention

Lower body negative pressure (LBNP).

Study burden and risks

The study is not a great burden for study subjects. There is a possibility that the application of LBNP will be experienced as uncomfortable. There is a minimal chance that study subjects lose consciousness. The direct release of LBNP will result in a fast recovery, without any remaining complaints.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- age: 18-35 years and >70 years
- non-smoking
- body mass index: 18-28 kg/m2
- length: 160-190 cm

Exclusion criteria

- medical history of cardiovascular disease, diabetes mellitus, pulmonary disease, neurological disease, malignant disease, venous insufficiency
- alcohol use >3 units / day
- use of systemic medication
- cognitive impairment (MMSE score < 28 points)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-05-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	29-05-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL27396.058.09