Non-invasive assessment of human ventricular-vascular function

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To establish the accuracy and precision of systolic cardiac time intervals and arterial pulse wave velocity as obtained from multiple M-mode carotid artery ultrasonography. And to test whether the non-invasive tonometer pressure waveform is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33840

Source
ToetsingOnline

Brief title
Non-invasive assessment of human ventricular-vascular function

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
coronary artery disease, ischemic cardiomyopathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: NWO Vernieuwingsimpuls Veni,Senter;Ministerie van Economische Zaken

Intervention

Keyword: Aging, Arterial stiffness, Hemodynamics, Ultrasound

Outcome measures

Primary outcome

Arterial pulse wave velocity (PWV), arterial distensibility, and left ventricular isovolumic contraction and ejection durations in a cohort with overt cardiovascular disease; agreement between non-invasive (ultrasonographic and tonometric) and invasive (gold standard) methods.

Secondary outcome

Details medical file: blood pressure measured in out-patient clinic

Study description

Background summary

Cardiovascular events, such as heart attacks and stroke, are secondary to chronic processes that alter cardiac and vascular structure and function (remodelling). Early recognition of underlying adverse remodelling is key in combating cardiovascular disease and the associated morbidity and socio-economic burden. Screening and timely diagnosis of cardiovascular disease in the general population requires accurate, reproducible, and applicable (non-invasive) assessment methods and technology. Non-invasive methods need to be validated against (invasive) gold standards in a relevant clinical population.

Study objective

To establish the accuracy and precision of systolic cardiac time intervals and arterial pulse wave velocity as obtained from multiple M-mode carotid artery ultrasonography. And to test whether the non-invasive tonometer pressure waveform is comparable to the invasively measured pressure waveform.

Study design

Prospective observational cross-sectional study involving paired measurements

within subjects.

Study burden and risks

Study is group-related in the sense that the experimental/technical requirements are met by the clinical diagnostic protocol. In other populations these measurements are not performed or not simultaneously, or obtained with insufficient measurement accuracy, are subject to intolerable variability or extreme pharmacological or mechanical control (surgery), or are deemed unethical in terms of risks and discomfort. Patients have to allow the ultrasonographer to perform imaging of the carotid artery during the angiographyprocedure. The additive risk and discomfort due to ultrasound imaging of the CCA is considered negligible with respect to the normal risks and discomfort involved in the angiographyprocedure.

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

Inclusion criteria are predefined by study population: All patients referred for coronary angiography.

Exclusion criteria

Obesity precluding ultrasonic and tonometric investigation of the common carotid artery.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2007
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	04-05-2009
Application type:	Amendment
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
CCMO	NL19856.068.07