Non-invasive model-based assessment of individual cardiovascular interaction

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To setup and validate an accessible, non-invasive method to enable earlier and more precise classification of patients with an elevated or high blood pressure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON35052

Source
ToetsingOnline

Brief title
Non-invasive assessment of individual cardiovascular interaction

Condition

- Cardiac disorders, signs and symptoms NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arteriosclerosis, high blood pressure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: NWO Vernieuwingsimpuls Veni - STW10261

Intervention

Keyword: Arterial stiffness, Cardiovascular interaction, High blood pressure

Outcome measures

Primary outcome

1. Agreement between existing (clinically used) methods and newly developed methods for determining: arterial wall properties (distensibility as function of pressure) and left ventricular geometry (dilated or not, wall thickened or not).

2. Reproducibility of the new methods, which determines the ability to track changes in functional and structural aspects of cardiovascular interaction over time.

Secondary outcome

Possible contribution of the new methods to the clinical diagnosis and treatment of hypertensive patients. (By retrospective analysis by physician.)

Study description

Background summary

High blood pressure is a risk factor for occurrence of stroke and myocardial infarction. Clinical management of high blood pressure strongly depends on diagnostic findings. A thickened cardiac muscle wall, as assessed by echocardiography, indicates the heart has been pumping against a higher pressure for sometime already. Such findings, in combination with well-documented high blood pressure, determine the kind of treatment (aggressive/conservative). However, relevant diagnostic methods are too comprehensive and costly to use in many patients.

Study objective

To setup and validate an accessible, non-invasive method to enable earlier and more precise classification of patients with an elevated or high blood pressure.

Study design

The study investigates possibilities to assess cardiovascular condition by a limited number of non-invasive measurements. Carotid artery diameter and the local blood pressure curve will be measured, providing direct information on arterial distensibility. The measurement data will be fed to a biomechanical/physiological computermodel to obtain an estimate of the condition of the heart. Standard clinical echocardiography will serve as a benchmark.
Comparative methods will be used to evaluate agreement between existing and new methods within each individual and over a follow-up period. Reproducibility and accuracy of the new methods are thus determined.

Study burden and risks

Quite small: measurement methods are non-invasive and pose minimal burden. Required extra time of the patient (in total 3 times 1 hour, spread over 6-9 months) is limited, because other clinical assessments take place at the same days on which the patient is already visiting the hospital or outpatient clinic.

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

documented high blood pressure, age above 18

Exclusion criteria

pregnancy, intended pregnancy, hypertensive urgency or emergency, cardiac arrhythmias, severe obesity precluding echo and tonometric assessment

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-02-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	20-08-2010
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
CCMO	NL31582.068.10