Autonomic response detection through Non-invasive beat-to-beat recording during Self-blood pressure measurement In Adults

Published: 26-04-2016
Last updated: 16-04-2024

The main goal is to assess differences in the maximal BP response compared to baseline using beat-to-beat registration of BP between subjects with and without established differences between home and ambulatory BP of at least 10/5 mmHg. As a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular hypertensive disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42901

Source
ToetsingOnline

Brief title
ANSIA

Condition

- Vascular hypertensive disorders

Synonym
blood pressure monitoring, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anxiety, Autonomic Response, Blood Pressure Monitoring, Hypertension

Outcome measures

Primary outcome

The principal parameter is the difference in the maximal BP response between subjects with and without previously established BP differences during self-measurement of at least 10/5 mmHg compared to baseline values.

Secondary outcome

As secondary parameters we will consider the difference in HRV and BRS between subjects with and without incremental BP differences during self-measurement compared to basal values of at least 10/5 mmHg.

Study description

Background summary

The diagnosis of hypertension is hampered by intrinsic blood pressure (BP) variability and anxiety responses that may systematically influence BP measurement. Both influence the diagnostic value of BP measurement and the prediction of cardiovascular disease. Anticipating a BP reading could induce a pressor response at home as may happen in the clinic. Such an *auto-cuff* response may be less significant during ambulatory BP measurement, where recording is nearly continuous and less influenced by emotional factors such as anxiety. We recently showed that differences between home and ambulatory BP do not relate to hypertensive organ damage. In addition, patients with a difference between home and ambulatory BP more frequently had a white coat effect. This suggests that anxiety responses upon the self-measurement of BP may exist. However, at present evidence regarding the possibility of such an *auto cuff *response based on the self-measurement of BP is lacking.

Study objective

The main goal is to assess differences in the maximal BP response compared to baseline using beat-to-beat registration of BP between subjects with and without established differences between home and ambulatory BP of at least 10/5 mmHg. As a secondary objectives we will assess the difference in HRV and BRS between subjects with and without incremental BP differences between home and ambulatory BP of at least 10/5 mmHg.

Study design

This study is designed as a single centre, one visit only, observational study. After screening for eligibility and given informed consent, all subjects will undergo cardiovascular risk assessment. Thereafter, all subjects will undergo a 30 minutes continuous non-invasive finger arterial BP recording and meanwhile 10 consecutive self-BP measurements.

Study burden and risks

The results of this study will contribute to improve the quality of BP monitoring and to better understand the characteristics of self-BP measurement responses in order to better identify susceptible subjects. Individual subjects will gain no direct benefit from this study. The risk and burden of participating in this study is negligible since all the measurements that will be performed are safe and non-invasive and the study comprises only one visit of approximately 1 hr.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1055AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1055AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Any subject who was previously enrolled in the home vs ambulatory BP study (AMSTERDAM study, NL 40014.018.12)

Exclusion criteria

* Pregnancy
* Severe heart rate irregularities of any cause
* Not able to follow instructions for BP measurement for any reason
* Inability or unwillingness to comply with the protocol requirements, or deemed by investigator to be unfit for the study

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):	12-05-2016
Enrollment:	50

Type:	Actual

Ethics review

Approved WMO Date:	26-04-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL57135.018.16