A Multi-centre Study To Evaluate the auto-cuff Response During home vs Ambulatory bp Monitoring

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

Summary

ID

NL-OMON37664

Source
ToetsingOnline

Brief title
AMSTERDAM

Condition

- Vascular hypertensive disorders

Synonym
elevated blood pressure, 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: Ambulatory blood pressure measurement, Auto-cuff response, Blood pressure measurement, Home blood pressure measurment

Outcome measures

Primary outcome

Prevalence of the auto-cuff response (defined as a higher average BP on HBPM *10 mmHg systolic or *5 mmHg diastolic compared to daytime ABPM) and their relation to demographic variables, cardiovascular risk factors and target organ damage defined as proteinuria

The difference in systolic BP between nocturnal HBPM and ABPM readings (AMSTERDAM at Night substudy).

Secondary outcome

- Prevalence of auto-cuff hypertension, defined as having an elevated home BP (*135 mmHg systolic or *85 mmHg higher diastolic) and a normal daytime ambulatory BP (defined as <135 mmHg systolic and <85 mmHg diastolic) and the relation to demographic variables, cardiovascular risk factors and target organ damage defined as proteinuria.

- Reproducibility of the auto-cuff response and auto-cuff hypertension

- The difference in diastolic BP between nocturnal HBPM and ABPM readings (AMSTERDAM at Night substudy).

- Reproducibility of nocturnal HBPM readings (AMSTERDAM at Night substudy)

- The accuracy of nocturnal BP measurements to detect non-dipping patients,

defined as a <10% nocturnal BP fall between daytime and night-time average BP

on ABPM (AMSTERDAM at Night substudy)

Study description

Background summary

In the management and diagnosis of hypertension, home blood pressure measurement (HBPM) and ambulatory blood pressure measurement (ABPM) show better reproducibility and correlation with target organ damage than clinical office blood pressure (BP) readings. There are, however, no studies reporting in detail about the predictive value of BP differences between HBPM and ABPM. There is one study reporting about patients with a difference in BP between ABPM and HBPM, suggesting that patients with an elevated HBPM compared with a normal ABPM might be at increased risk of cardiovascular death. However, these data are inconclusive and reliable data about the prevalence and associated patient characteristics are lacking. We postulate that this phenomenon is a variant of the white-coat effect, and that these patients are actually not at increased risk despite an elevated HBPM, and thus need to BP follow-up only at ABPM. Therefore, the current study aims to provide data about the prevalence, predictive value and clinical relevance of this phenomenon, which we refer to as the auto-cuff response because these patients seem to respond to placing the BP cuff around their arms. The study also aims to provide information on the demographic characteristics and cardiovascular risk factors associated with the auto-cuff response.
Current HBPM devices do not allow for nocturnal BP readings. Recently, a HBPM device which allows several nocturnal readings has been introduced. Therefore, the current study also assesses the difference in BP between nocturnal HBPM and ABPM readings in a subgroup of patients.

Study objective

This study has two principal aims. The first aim is to establish the relation between the auto-cuff response and target organ damage defined as difference in microalbumin/creatinin ratio. The second aim is to assess the difference in BP between nocturnal HBPM and ABPM readings (AMSTERDAM at Night substudy).

Study design

A multi-centre open label crossover study in which seven hospital visits are planned. When a patient is referred to HBPM or ABPM, the doctor will briefly inform the patient on the current study and contacts one of the investigators. The investigators contact the patient and informs him or her about the nature of the study. If a patient is deemed eligible and is interested in the study, the patient information folder will be send. The investigator will then again contact the patient within approximately one week to answer potential questions. If patient is still willing to participate, an appointment will be scheduled.for the first visit. In the first visit, which last approximately 30 minutes, patient will again be informed on the study and informed consent will be signed if the patient is wiling to participate. Then a questionaire will be taken, and length and weight are recorded. Subsequently the patient will be informed on the HBPM, and three supervised measurement will be recorded (office BP measurement). An appointment for the delivery of the urine sample will also be made, which co-incdes with one of the next visits. Patients also recieve the anxiety questoinaires. After a week of HBPM, patients return for visit two to recieve instruction on the 24h measurement. Data of the first HBPM week will also be retrieved from the memory, so it can be cleared an given back to the patient for the next week of HBOM. If it is not possible to read out the information another device will be given, and instructions ons HBPM will be briefly repeated. This visit lasts approximately 25 minutes. After this visit the patient starts the ABPM. In visit three the patient returns the ABPM device, which lasts about 5 minutes. In the fourth and final visit the patient returns the HBPM device, which also takes about 5 minutes.
Due to a shortage of ABPM devices it is not possible to let the patient keep the ABPM device until returning the HBPM device.

Study burden and risks

The burden of this study consists of a total of four visits, totaling approximately 65 minutes. The techniques used are a 24h ABPM, and HBPM. Furthermore an anxious state and trait questionnaire (an adapted Dutch version of the Spielberger State-Trait Anxiety Inventory (STAI) for state and a visual analogue scale (VAS) and a Dutch short form of the state scale of the STAI) will be taken. Length, weight, waist circumference and an office BP (OBP) will be assessed. The other BP measurements will be performed at home, but patients need to be informed and instructed how to appropriately use the home or ambulatory BP devices, which will find place within the selected study centers. Additionally, a morning urine sample will be collected.
These measurements are considered safe. Most discomfort is expected to arise from the 24h measurement, in which some patients complain about waking up from the inflating cuff. This might also account for the nocturnal HBPM readings, although there will be performed only three readings for one night per HBPM session.

During the study patients are not allowed to change their blood pressure lowering medication. Therefore, there is a risk some patient will have an elevated BP for a maximum period of four weeks during the study in which their BP lowering regiment can not be changed. However, in most patients the BP is already increased for a prolonged period, and prolonging that period with a few more weeks is not expected to affect their prognosis. One exception is a hypertensive crisis in which case the study is terminated.

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

Reffered to Home Blood Pressure Measurement or Ambulotory Blood Pressure Measurement, irrespective of the indication.

Exclusion criteria

Severe heart rate irregularities of any cause
Pregnancy
Not able to follow instructions for HBPM or ABPM for any reason

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):	11-10-2012
Enrollment:	450
Type:	Actual

Ethics review

Approved WMO Date:	30-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-12-2012
Application type:	Amendment
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	NL40014.018.12