Self-initiated versus fully automated method for the measurement of blood pressure at home

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45921

Source
ToetsingOnline

Brief title
Assessing the 'auto-cuff' response at home

Condition

- Other condition

Synonym
high blood pressure, Hypertension

Health condition

hypertensie

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 (ABPM), Auto-cuff response, Home Blood Pressure Measurement (HBPM), Hypertension

Outcome measures

Primary outcome

The chief parameter we will be studying is the difference in average systolic

blood pressure (in mmHg), defined as the mean systolic blood pressure measured

with the self-initiated method compared to the mean systolic blood pressure

measured with the fully-automated method.

Secondary outcome

Secondary parameters we will study are:

- The difference in average diastolic blood pressure (in mmHg), defined as the

mean diastolic blood pressure measured with the self-initiated method compared

to the mean diastolic blood pressure measured with the fully-automated method;

- The difference in average heartrate (in beats/minute).

Study description

Background summary

Hypertension plays a large role in cardiovascular disease, the world*s leading cause of death. The need for accurate detection therefore seems obvious. There is considerable evidence that HBPM and ABPM are more accurate and precise in diagnosing hypertension and better predict clinical outcomes compared to office BP measurement. However, recent studies show that these two types of measurement are not interchangeable: HBPM frequently shows higher average blood

pressure values compared to daytime ABPM, although this is not associated with an increase in cardiovascular disease risk or hypertensive organ damage. We recently showed that self-initiated BP measurement results in a higher blood pressure compared to fully-automated measurements, suggesting an anticipatory reaction to self-measurement called the 'auto-cuff' response. This has only been studied in an in-office setting. In the present proposal our aim is to examine differences in blood pressure between self-initiated blood pressure readings and fully-automated measurement in an out-of-office setting. We hypothesize that there is an anticipatory reaction with self-initiated blood pressure measurements, albeit possibly not with as much of a blood pressure difference as in our previous study.

Study objective

The main goal is to assess the difference in average systolic bloodpressure between self-initiated and fully automated measurement, thereby evaluating the influence of the *auto-cuff* response in an out-of-office setting. Secondary goals are assessing the difference in average diastolic blood pressure and heartrate.

Study design

This study is designed as a single centre, two-visit, cross-over study. After screening for eligibility and given informed consent, all subjects will fill in a questionnaire and cardiovascular risk will be assessed. Subsequently, all patients will perform blood pressure measurement twice daily, by both the self-initiated as well as by the fully-automated method over the course of 10 weekdays.

Study burden and risks

The results of this study are beneficial to our understanding and application of blood pressure measurement in an out-of-office setting, increasing quality of blood pressure monitoring and thereby increasing capability to identify and treat susceptible subjects. The burden and risks of participation are negligible, considering all measurements are safe and non-invasive. Moreover, the study comprises of only two short visits of approximately 20 minutes each including questionnaire and instructions, in addition to self-measurement at home for a total of 10 weekdays, taking up about 15 minutes each day. There is no individual benefit from participation in this study.

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

- Aged *18 years;
- Patient visiting the outpatient clinic of the Department of Cardiology and Department of Internal/ Vascular Medicine of the AMC.

Exclusion criteria

- Pregnancy;
- Severe heart rate irregularities of any cause;
- Severe uncontrolled hypertension (mean BP>200/120 mmHg in the clinic);
- Not able to follow instructions for BP measurement for any reason;
- Recently changed BP lowering medication (<4 weeks);
- 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
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-09-2018
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	27-08-2018
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	NL66678.018.18