Ambulant versus unattended & attended office versus self-home blood pressure measurement

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Objective: Primary: To investigate the agreement between HBPM and ABPM for measuring BP in patients with hypertension. Secondary:a) To investigate the agreement between HBPM and daytime ABPM for measuring BP in patients treated for hypertensionb) To...

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

Summary

ID

NL-OMON55589

Source
ToetsingOnline

Brief title
AMUSE-BP

Condition

- Vascular hypertensive disorders

Synonym
Hypertension en high blood pressure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Medicine Men B.V. ,Retomed Health B.V.

Intervention

Keyword: Ambulatory, Blood pressure, Hypertension, Self-monitoring

Outcome measures

Primary outcome

Main study parameters/endpoints: The main study parameters are twofold:

(1) Mean difference between HBPM and ABPM values calculated with the

Bland-Altman method

(2) Mean standard deviation (SD) of the mean difference between HBPM and ABPM

calculated with the Bland-Altman method.

- Both expressed in mmHg for both SB and DBP (see primary objective chapter 2).

- The HBPM value is a 7-day average of systolic and diastolic BP

- The ABPM value is an average BP measured by 24-hour ambulatory measurements

Secondary outcome

For all of the secondary objectives formulated in chapter 2 (objective A, B, C,

D, E, F, G, H, I, J) the study parameters are the same as the main study

parameters.

For the last secondary objectives K the study parameters are:

K: To investigate if a different protocol than the standard 7-day HBPM protocol

results in clinically acceptable (<3 mmHg) average systolic and diastolic BP

readings as compared to the ABPM.

We will test the agreement for variable number of days combined with discarding

morning or evening measurements. The agreement will again be expressed as mean

difference and standard deviation of the differences between HBPM and ABPM.

Also, an area under the curve analysis will be performed.

Other study parameters:

Baseline information will be collected from all participants: age, sex, arm

circumference, medical history, BMI, medication, smoking status

Study description

Background summary

CVD remains the leading cause of death globally (31,4%). Ischemic heart diseases (16.6%), followed by stroke (10.2%) account for 85% of all CVD-related deaths. High BP is the dominant risk factor for CVD. Prevalence of high BP globally is a staggering 31% for all adults. For people over 65 years of age the prevalence rises above 50% and reaches values of 70%.

Discussion about treatment thresholds and which BP measurement methods to use, especially in different patient subpopulations and age categories, has always been a topic of scientific debate. Recently the *Systolic BP Intervention Trial* (SPRINT) has complicated this discussion even further by unintentionally adding another factor into the mix: the protocol of BP measurement methods. The initial results of the SPRINT-trial were compelling. However, a debate about the method used to measure BP in the trial quickly ensued and caused concerns about the generalizability of the results into clinical practice. How did their unattended automated BP method compare to the most used conventional (attended and semi-automated) BP method? And what does this mean for the generalizability of the compelling results? The 120 mmHg systolic BP measurement threshold might even be equivalent to 140 mmHg using conventional office BP methods critical investigators argued.
The discussion about the method of BP measurement is very relevant as more and more BP devices in clinical practice use automated measurements. The problem however is that each device has different hardware installed and per manufacturer the software algorithms for determining BP after multiple readings are different (and often secret for marketing purposes). On top of that, many different instruction protocols for measuring BP exist. Variation can be seen on the time rested before taking the actual measurement, posture of the

participant, attended versus unattended, the number and time between measurements, single or both arm measurements and on-site circumstances (clinic versus home). So, each method has their own unique way of measuring BP. Creating a subset of uniquely different BP measurements within a single patient. Considering all of the above and the fact that office BP measurements cannot detect the important hypertension phenotypes white coat and masked hypertension, we should search for better implementation of more reliable and better reproducible BP methods such as out-of-office BP measurements.
There is consensus out-of-office BP measurement methods, either ABPM or HBPM, are the best methods to diagnose and follow up hypertension. ABPM however is cumbersome, time consuming and expensive. HBPM is considered a more patient friendly alternative and cheaper than ABPM. The recent updated guidelines for the management of arterial hypertension (ESC/ESH 2018) advice the use of ABPM and HBPM interchangeably when performing out-of-office BP measurement. HBPM leads to significantly better BP control. The effect on BP control is even bigger when self-monitoring is accompanied by other (co)interventions such as telemonitoring and app support.

The UMC Utrecht has developed a new, state of the art, method for HBPM. An important feature is the integration of a protocolled 7-day measurement as advised by the ESH practice guidelines for home blood pressure monitoring. This 7-day protocol, which leads to a standardized 7-day BP average, is also advised as the preferred HBPM method protocol in the already mentioned recent updated guidelines for management of arterial hypertension.
Our HBPM method uses a validated BP measurement device together with a newly developed CE certified app. The app provides the user BP measurement instructions and, among other things, visual representation of BP values, cloud storage, facilitates remote telemonitoring services, in-app messaging functions and reminder options (email, text message or in-app notifications). Our HBPM method is state of the art and innovative because it uses a combination of validated hardware, ICT techniques and an evidence based guideline-advocated BP measurement protocol not seen before to our knowledge.
In light of the discussion earlier about troublesome heterogeneity of BP methods and protocols, we designed the AMUSE-BP study. The AMUSE-BP aims to compare the agreement between the five most used modern BP methods in a randomized five-way crossover design. Our primary objective will be the comparison, expressed as the agreement, between ABPM and our newly developed HBPM method. The five BP methods used are: ABPM, attended and unattended automatic office BP management (a/u-AOBP), HBPM and 30mBP. Results of the AMUSE-BP study will help researchers answer the question if and how we can use our newly developed HBPM method in comparison with ABPM and different office BP measurements for the treatment of patients with raised blood pressure.

Study objective

Objective:
Primary:

To investigate the agreement between HBPM and ABPM for measuring BP in patients with hypertension.

Secondary:

a) To investigate the agreement between HBPM and daytime ABPM for measuring BP in patients treated for hypertension

b) To investigate the agreement between HBPM and a-AOBP for measuring BP in patients treated for hypertension.

c) To investigate the agreement between HBPM and u-AOBP for measuring BP in patients treated for hypertension.

d) To investigate the agreement between HBPM and 30mBP for measuring BP in patients treated for hypertension.

e) To investigate the agreement between ABPM and a-AOBP for measuring BP in patients treated for hypertension.

f) To investigate the agreement between ABPM and u-AOBP for measuring BP in patients treated for hypertension.

g) To investigate the agreement between ABPM and 30mBP for measuring BP in patients treated for hypertension.

h) To investigate the agreement between attended AOBP and u-AOBP for measuring BP in patients treated for hypertension.

i) To investigate the agreement between a-AOBP and 30mBP for measuring BP in patients treated for hypertension.

j) To investigate the agreement between unattended AOBP and 30mBP for measuring BP in patients treated for hypertension.

k) To investigate if a different protocol instead of a standard 7-day HBPM protocol results in clinically acceptable (<3 mmHg) average systolic and diastolic BP readings as compared to the ABPM and awake ABPM

Study design

The study will have a controlled randomized 5-way cross-over design. The 5 different periods each contain 1 out of 5 different BP methods:

(1) HBPM (7-day home measurement)

(2) ABPM (24-hours)

(3) a-AOBP (single office measurement visit)

(4) u-AOBP (single office measurement visit)

(5) 30-minute AOBP (single 30-minute unattended office measurement visit)

Study burden and risks

Patients will be asked to participate in a randomized 5-way crossover design study with a total of 5 different BP methods (corresponding with the *5-way* as described above). Total length of the study will be a minimum of 15 and a maximum 29 days, depending on the randomization arm and planned measurement schedule. All BP methods are safe, already used in clinical practice in all participating centers and generally very well accepted by patients. Elevated BP is the dominant risk factor for the development of cardiovascular disease, which is in turn the number one cause of death worldwide. Patients treated for hypertension need frequent BP measurements for follow-up and therefore participation in this study is fully justifiable. No new or prolonged methods other than already used by healthcare professionals will be used. All methods are performed with CE certified and validated BP devices and by authorized and trained local personnel. Potential benefit for the participants is insight in available BP methods and corresponding BP values. High acceptability of patients for BP devices and methods improves adherence too. Patients in this study could benefit from new insights in different BP methods and through shared decision making choose their own preferred BP measurement method for follow-up.

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

1. Age of 18 years or older
2. Documented medical history of hypertension in local hospital electronic patient record
3. Stable dose of anti-hypertensive medication for at least 2 months (includes no current antihypertensive medication, diagnosis hypertension is enough)
4. SBP>90 and <180 mmHg and DBP >60 and <110mmHg at inclusion screening attained by attended AOBP
5. Dutch and/or English language capable for reading patient information letter and in-app instructions.
6. Smartphone or tablet owner with either iOS or Android installed as operating system. Operating system requirements: iOS 8.0 or higher, Android version 4.1 or higher.

Exclusion criteria

1. SBP >180 mmHg and/or DBP >110mmHg at inclusion screening visit (attended AOBP).
2. Any BP that according to the treating physician is not adequately controlled and needs medication adjustment < 2 months or within the study time period.
3. Recent (<2 months) anti-hypertensive medication changes (including diuretics).
4. Recent start or change in dosing of alpha-blockers prescribed for other purpose than blood pressure control (for example benign prostate hypertrophy).
5. Unstable or uncontrolled endocrine disease (e.g. thyroid disease, Cushing*s or Addison*s disease) with the exception of diabetes mellitus.
6. Persistend arrhythmias that prevent any BP measurement device to correctly measure BP during inclusion screening visit; such as supraventricular

arrhythmias or atrial ventricular block. Known arrhythmias, but not clinically present during inclusion screening is not an exclusion criterion.
7. Heart failure grade 2 or higher on the New York Heart Association (NYHA) Functional Classification.
8. Documented missed outpatient clinic appointments (2 or more the last 6 months).
9. Documented therapy non-adherence (e.g. biochemical proven medication non-adherence, known or highly suspected medication non-adherence by treating physician, proven direct observed therapy effect in BP).
10. Participants cannot plan a measurement schedule with a minimum of 21 and a maximum of 29-day period participation or a minimum of 4 and maximum of 5 hospital visits due to logistical issues or scheduling issues of any kind.
11. Physical inability to perform an home BP measurement, use the Microlife A6 BT BP device and or Microlife@Home app.
12. For Women: active pregnancy or planning trying to get pregnant during the study period.

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):	10-02-2020
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	EmmaHBPM app
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-09-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	06-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-03-2021
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29341
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL61791.041.19
OMON	NL-OMON29341