A randomized cross-over study to investigate the agreement betwen 24-hour ambulant blood pressure monitoring, home blood pressure monitoring, unattended&attended automated office and 30-minute blood pressure monitoring, unattended & attended automated office and 30-minute blood pressure measurment in patients treated for hypertension

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29341

Source
NTR

Brief title
AMUSE-BP

Health condition

Hypertension

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: UMC Utrecht, Retomed Health B.V., Medicine Men B.V.

Intervention

Outcome measures

Primary outcome

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 SBP and DBP
- The HBPM value is composed of a 7-day average of systolic and diastolic BP
- The ABPM value is composed of the average BP calculated by 24-hour ambulatory measurements

Secondary outcome

1. the agreement between HBPM and daytime ABPM for measuring BP in patients treated for hypertension
2. the agreement between HBPM and attended AOBP for measuring BPin patients treated for hypertension.
3. the agreement between HBPM and unattended AOBP for measuring BP in patients treated for hypertension
4. the agreement between HBPM and 30m BP for measuring BP in patients treated for hypertension
5. the agreement between ABPM and attended AOBP for measuring BP in patients treated for hypertension
6. the agreement between ABPM and unattended AOBP for measuring BP in patients treated for hypertension
7. the agreement between ABPM and 30m BP for measuring BP in patients treated for hypertension
8. the agreement between attended AOBP and unattended AOBP for measuring BPin patients treated for hypertension
9. the agreement between attended AOBP and 30mBP for measuring BPin patients treated for hypertension
10. the agreement between unattended AOBP and 30mBP for measuring BPin patients treated for hypertension.

Study description

Background summary

Objective: to compare our newly developed home blood pressure measurment (HBPM) method with the current gold standard 24-hour ambulatory blood pressure monitoring (ABPM) and the most used office BP measurement methods

Study design: randomised controlled 5-way cross-over

Study population: patients with documented medical history of hypertension who visit outpatient clinic

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 SBP and DBP
- The HBPM value is composed of a 7-day average of systolic and diastolic BP
- The ABPM value is composed of the average BP calculated by 24-hour ambulatory measurements

Study objective

Home blood pressure measurement and 24 hour ambulatory blood pressure monitoring will be in good agreement with each other

Study design

Inclusion, follow-up visit (between 15 -21 days after randomisation)

Contacts

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Scientific
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Eline Groenland

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Eligibility criteria

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 antihypertensivemedication, diagnosis hypertension is enough)
4. SBP>90 and <180 mmHg and DBP >60 and <110mmHg at inclusion screening attained by attended office blood pressure measurement
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 systemrequirements: 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 (forexample benign prostate hypertrophy).
5. Unstable or uncontrolled endocrine disease (e.g. thyroid disease, Cushing’s or Addison’s disease) with theexception of diabetes mellitus.
6. Persistend arrhythmias that prevent any BP measurement device to correctly measure BP during inclusionscreening visit; such as supraventricular arrhythmias or atrial ventricular block. Known arrhythmias, but notclinically 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 highlysuspected 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 periodparticipation or a minimum of 4 and maximum of 5 hospital visits due to logistical issues or scheduling issues ofany kind.
11. Physical inability to perform an home BP measurement, use the Microlife A6 BT BP device and orMicrolife@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
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	08-01-2020
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	08-01-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55589
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8277
CCMO	NL61791.041.19
OMON	NL-OMON55589

Study results