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

Gepubliceerd: 08-01-2020 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29341

Bron
NTR

Verkorte titel
AMUSE-BP

Aandoening

Hypertension

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: UMC Utrecht, Retomed Health B.V., Medicine Men B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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
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- 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

Doel van het onderzoek

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

Onderzoeksopzet

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

Contactpersonen

Publiek

UMC Utrecht
Eline Groenland

0887555651

Wetenschappelijk

UMC Utrecht
Eline Groenland

0887555651

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	08-01-2020
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	08-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55589
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten