Accuracy of sequential versus simultaneous BP measurement in assessing between-arm BP differences using the Microlife Watch BP Office

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- To elucidate whether simultaneous measurement of brachial BP may improve the accuracy of assessment of interarm BP differences compared with sequential interarm BP assessment

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

Summary

ID

NL-OMON37725

Source
ToetsingOnline

Brief title
Simultaneous vs Sequential IABPD

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: blood pressure, blood pressure assessment, interarm blood pressure difference

Outcome measures

Primary outcome

Difference in interarm BP difference in mmHg between sequential and

simultaneous BP measurements

Secondary outcome

Difference in interarm BP difference in mmHg between sequential and

simultaneous BP measurements between different risk groups

The association between interarm BP differences and cardiovascular risk factors

To compare the number of patients with a large inter-arm BP difference (>=20

mmHg or >=10 mmHg systolic or >= 10 mmHg or >= 5 mmHg diastolic) between

sequential en simultaneous measurements

To evaluate whether the BP rises during the simultaneous BP measurements

compared with sequential measurements

Study description

Background summary

Inter-arm blood pressure (BP) differences have been established since the early '20's of last century. Large inter-arm BP differences have been associated with peripheral vascular diseases and reduced 10-year survival. Therefore, the European Society on Hypertension, as well as the European Society of Cardiology

recommend in their guidelines to measure BP at both arms at a patients first visit. The higher value should then be taken as a reference. Interestingly, despite these clear recommendations, the guidelines do not tell how the inter-arm BP difference should be assessed. Previous studies have shown that simultaneous measurements are favored over sequential measurements, as the number of patients with a large inter arm BP differences is smaller in the same population. However, these data are based on studies in which simultaneous measurements are - at best - taken by two similar BP devices. Recently a new BP measurement device was introduced, with the possibility to simultaneously measure the BP at both arms using two cuffs (Watch BP Office). This device also allows for sequential BP measurements at both arms individually. Therefore, we used this device to compare sequential with simultaneous interarm BP differences.

Study objective

- To elucidate whether simultaneous measurement of brachial BP may improve the accuracy of assessment of interarm BP differences compared with sequential interarm BP assessment

Study design

Prospective open-label crossover study including 300 persons distributed over four different risk profile group. The risk groups are strafied according to their age and blood presssure (see study population)

Study burden and risks

Inter-arm differences relate to and peripheral vascular diseases and all cause mortality. Assessment of inter-arm BP differences may serve as a cheap, non-invasive tool to assess cardiovascular risk. Sequential measurement of inter-arm BP difference is hampered by order effects. The simultaneous assessment of inter-arm BP difference) might overcome these problems, possibly increasing the predictive value of inter-arm BP measurements as a marker for atherosclerosis.

The benefit following participation includes recording of cardiovascular risk factors and a standardized BP reading. These will be communicated to the patient and to their doctor*s. The study burden consists of a brief questionnaire to assess cardiovascular risk and a series of 6 consecutive BP measurements. These measurements are not invasive and do not harm the patients.

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

Age: 18-50y or ><= 60y

Exclusion criteria

Smoking < 1h before measurement
Drinking of alcohol < 12h before measurement
Drinking of coffee <1 h before measurement

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):	16-07-2012
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	16-07-2012
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	NL40165.018.12