Validation and comparison of four smartphone-connected blood pressure monitors

Published: 06-05-2015
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To validate and compare smartphone-connected blood pressure monitors produced by Withings, Qardio and iHealth with the gold standard and a validated automatic blood pressure monitor.

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

Summary

ID

NL-OMON42703

Source
ToetsingOnline

Brief title
Comparison of four smartphone-connected blood pressure monitors

Condition

- Vascular hypertensive disorders

Synonym
high blood pressure, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: blood pressure, cuff, monitor, smartphone

Outcome measures

Primary outcome

All blood pressure measurements by all devices.

Secondary outcome

Not applicable

Study description

Background summary

Smartphone-connected blood pressure monitors are being released on the market. An independent study comparing the accuracy of these devices has not been done yet.

Study objective

To validate and compare smartphone-connected blood pressure monitors produced by Withings, Qardio and iHealth with the gold standard and a validated automatic blood pressure monitor.

Study design

Clinical trial in which 67 people will receive 18 blood pressure measurements by 6 different devices (three measurements per device)

Study burden and risks

Not applicable

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

Population 1:
- young, healthy individuals
- age: 18-30;Population 2:
- patients with a STEMI and primary PCI one year or less ago at the time of their outpatient clinic visit.

Exclusion criteria

Population 1:
- any diagnosed vasculitis
- any diagnosed congenital heart disease
- any first degree family member with a diagnosed inheritable cardiomyopathy;Population 2:
- patients with any diagnosed irregular cardiac arrhythmia

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):	28-05-2015
Enrollment:	67
Type:	Actual

Ethics review

Approved WMO

Date:	06-05-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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: 21902
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52863.058.15
OMON	NL-OMON21902

Study results

Date completed: 09-10-2015

Actual enrolment: 43

Summary results
Trial is onging in other countries