Validation and comparison of four smartphone-connected blood pressure monitors

Gepubliceerd: 01-06-2015 Laatst bijgewerkt: 15-05-2024

We hypothesize that the accuracy of four selected types of smartphone compatible blood pressure monitors does not differ significantly from the handheld sphygmanometer

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21902

Bron
Nationaal Trial Register

Verkorte titel
not applicable

Aandoening

Not applicable

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

All measured blood pressures by all devices

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.

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: Crossover trial

Study population: Two study populations will be investigated. The first population (population one) will consists of young, healthy individuals aged 18-30. The second population (population two) will consist of patients who visit the outpatient clinic within one year after having suffered from a ST elevation myocardial infarction for which they received primary percutaneous coronary intervention in the LUMC.

Intervention: All study subjects will receive three blood pressure measurements with a handheld manometer, three measurements with an automatic device and 12 measurements with 4 automatic devices (1 device will be used 3 times in 1 patient). The order in which the devices are used will be randomized

Main study parameters/endpoints: The study parameter will be per study subject 18 systolic blood pressure measurements (SBP), 18 diastolic blood pressure measurements (DBP) and 18 heart rates (HR).

Doel van het onderzoek

We hypothesize that the accuracy of four selected types of smartphone compatible blood pressure monitors does not differ significantly from the handheld sphygmanometer

Onderzoeksopzet

not applicable

Onderzoeksproduct en/of interventie

Four smartphone compatible blood pressure monitors:

- iHealth BP 5

- iHealth BP 7

- QardioArm

- Withings Blood Pressure Monitor

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with a ST-elevation myocardial infarction and subsequently primary percutaneous coronary intervention (PCI) one year or less ago at the time of their outpatient clinic visit.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with diagnosed irregular cardiac arrhythmias

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	28-05-2015
Aantal proefpersonen:	43
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-06-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42703
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5109
NTR-old	NTR5241
CCMO	NL52863.058.15
OMON	NL-OMON42703

Resultaten

Samenvatting resultaten
not applicable