# Validation and comparison of four smartphone-connected blood pressure monitors

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21902

**Source**
Nationaal Trial Register

**Brief title**
not applicable

**Health condition**

Not applicable

### Sponsors and support

**Primary sponsor:** Leiden University Medical Center
**Source(s) of monetary or material Support:** not applicable

### Intervention

### Outcome measures

**Primary outcome**

All measured blood pressures by all devices

**Secondary outcome**

not applicable

# Study description

### Background summary

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).

### Study objective

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

### Study design

not applicable

### Intervention

Four smartphone compatible blood pressure monitors:

- iHealth BP 5

- iHealth BP 7

- QardioArm

- Withings Blood Pressure Monitor

## Contacts

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## Eligibility criteria

### Inclusion criteria

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.

### Exclusion criteria

Patients with diagnosed irregular cardiac arrhythmias

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 28-05-2015 |
| Enrollment: | 43 |
| Type: | Anticipated |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 01-06-2015 |
| Application type: | First submission |

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 42703
Bron: ToetsingOnline
Titel:

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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| NTR-new | NL5109 |

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

# Study results

**Summary results**
not applicable