

BP@Home study

Does the blood pressure measured at the preoperative screening clinic represent the real blood pressure at home? An observational comparative cohort study using continuous blood pressure measurements at home

Published: 12-11-2018

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To compare the differences in blood pressure; between 24hr-blood pressure measurements at home and blood pressure measured at the pre-assessment clinic and just before start of surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON50510

Source

ToetsingOnline

Brief title

BP@Home study

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC

Synonym

Tension measurements

Health condition

Pre operative screening bij chirurgische ingrepen

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, Observational comparative cohort study, Pre Operative Screening vs Home

Outcome measures

Primary outcome

Primary Objective: to study to what extend 24-BP measurement at home differ from the BP measured at the pre-assessment clinic, at the ward and just before surgery

Secondary outcome

Secondary objective:

- to study to what extend 24-BP measurement at home differ from the BP measured at the pre-assessment clinic and just before surgery across different ranges of BP.
- to study to what extend a 5 minute BP measurement at the pre-assessment clinic differs from the single BP measured at the pre-assessment clinic and just before surgery
- to explore the characteristics of patients with and without differences in BP

measurements at different time points.

Study description

Background summary

The definition of perioperative hypotension differs and usually depends on the blood pressure (BP) as measured at pre-operative assessment or in the awake patient just before surgery. These measurements are obtained in patients preparing for surgery and might be influenced by stress or in-hospital anxiousness. We want to investigate to what extent 24-blood pressure (gold standard) measurements at home differ from the BP measured at the pre-assessment clinic and just before start of surgery.

Study objective

To compare the differences in blood pressure; between 24hr-blood pressure measurements at home and blood pressure measured at the pre-assessment clinic and just before start of surgery.

Study design

Single center observational cohort study

Study burden and risks

The risk for the patient is nil.

The burden on the patient is minimal. During 24hrs, a number of measurements are performed, during which the patient can perform his normal daily routine. After 24hr the investigation will stop, and the device will be returned to the AMC.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Adult patients, age 18-80 years inclusive
- Scheduled for elective surgery
- Willing and able to provide written informed consent

Exclusion criteria

- Emergency surgery or unscheduled surgery
- Patients with known or suspected pheochromocytoma or carcinoid tumor
- Patients with known disturbances in cortisol homeostasis
- Patients with known adrenal pathologies
- Underlying condition that does not allow patients to participate in the study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	04-12-2018
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO	
Date:	12-11-2018
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	NL66046.018.18