

Home versus Office blood pressure MEasurements: Reduction of Unnecessary treatment Study

Submission date 19/10/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Peter de Leeuw

Contact details
P Debyelaan 25
5800
Maastricht
Netherlands
6229 AZ
-
Ple@sint.azm.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

Home versus Office blood pressure MEasurements: Reduction of Unnecessary treatment Study

Acronym

HOMERUS

Study objectives

Antihypertensive treatment based on self measured blood pressure values may lead to less use of drugs without leading to worse blood pressure control or more target organ damage as compared to patients who are treated based on conventional office blood pressure measurement.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Informed consent, in accordance with the declaration of Helsinki, has been obtained from all patients prior to entering the study. Good clinical practice is maintained and the study protocol has been approved by the ethical committees of all participating centres before inclusion of patients into the study.

Study design

A multicentre prospective randomised clinical trial with a parallel group design. Patients are followed-up for a period of one year.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hypertension

Interventions

Group one: patients receive antihypertensive treatment on the basis of self blood pressure measurement.

Group two: patients are treated based on conventional office blood pressure measurement.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Blood pressure value (conventional office blood pressure and 24 hour ambulatory blood pressure)
2. Target organ damage (kidney, heart)
3. Cost and number of antihypertensive drugs

Key secondary outcome(s))

1. Compliance with treatment
2. Quality of life

Completion date

01/10/2004

Eligibility**Key inclusion criteria**

1. Males and females aged 18 years and above
2. Average blood pressure between 139 and 200 mmHg for systolic or between 90 and 120 mmHg for diastolic blood pressure
3. Participating subjects are physically and mentally able to measure their own blood pressure
4. Subjects are willing to remain in follow-up during a period of one year
5. Signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. The presence of clinically manifest cardiovascular events (angina pectoris, heart failure, hypertensive encephalopathy, or prior myocardial infarction or cerebrovascular accident)
2. Severe non-cardiovascular disease (e.g. malignancy), which will interfere with adequate follow up
3. Allergy or contra-indications for the antihypertensive drugs used in this study
4. Serum creatinine above 150 micromol/l
5. Clinically significant orthostatic hypotension (a drop in systolic blood pressure of more than 20 mmHg upon standing)
6. Blood pressure devices

Date of first enrolment

01/10/2001

Date of final enrolment

01/10/2004

Locations

Countries of recruitment

Netherlands

Study participating centre

P Debyelaan 25

Maastricht

Netherlands

6229 AZ

Sponsor information

Organisation

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands) (ref: 945-01-043)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2007		Yes	No
Results article		01/12/2007		Yes	No
Other publications		01/08/2003		Yes	No
Other publications		01/08/2005		Yes	No
Other publications		01/08/2006		Yes	No