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

Submission date	Recruitment status	[_] Prospectively registered
19/10/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2022	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
1. Compliance with treatment
2. Quality of life

Overall study start date
01/10/2001

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

430 (216 self-measured pressures, 214 office pressures)

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)

Sponsor details
PO Box 93245
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Sponsor type
Research organisation

Website
http://www.zonmw.nl/nl/home/contact.html

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Other publications		01/08/2003		Yes	No
Other publications		01/08/2005		Yes	No
Other publications		01/08/2006		Yes	No
Results article		01/12/2007		Yes	No
Results article		01/12/2007		Yes	No