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The impact of home blood pressure measurement on blood pressure control in the elderly

Submission date 21/09/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/10/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/10/2010	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2010-A00701-38

Study information

Scientific Title
A longitudinal, cluster randomised, study on the impact of home blood pressure measurement on blood pressure control in the elderly

Study objectives
That self measurement of blood pressure at home by elderly individuals may help to improve blood pressure control

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethics Committee (Comité de Protection des Personnes [CPP] Ile-de-France 7) approved on the 10th of June 1999 for the main cohort and on the 7th of July 2010 for the present study (ref: SC10-004)

Study design
Observational cluster randomised study

Primary study design
Observational

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Hypertension

Interventions
Patients to the clinic will be randomised by week, those visiting on even weeks will be assigned to:
1. Regular (every 3 months) self-measurement of blood pressure at home with an automatic device
Those visiting on odd weeks will be assigned to:
2. No regular self-measurement
The total duration of the intervention will be one year.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Difference of office mean values of systolic and diastolic blood pressure among hypertensives between both groups at the end of the intervention period (1 year)

Secondary outcome measures
1. Difference of home mean values of systolic and diastolic blood pressure among hypertensives between both groups
2. Difference of percentage of participants with hypertension between both groups
3. Difference of use of antihypertensive drugs between both groups
4. Frequency of masked and white coat hypertension and difference between both groups
5. Feasibility
All outcomes will be measured at the end of the intervention period (1 year)

Overall study start date
01/02/2010

Completion date
01/02/2011

Eligibility

Key inclusion criteria
Volunteers of an ongoing observational cohort study:
1. ≥ 65 year of age
2. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600 in each arm (total of 1200)

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/02/2010

Date of final enrolment

01/02/2011

Locations

Countries of recruitment
France

Study participating centre
Inserm U708
Paris
France
75651

Sponsor information

Organisation
National Institute of Health and Medical Research (Institut National de la Santé et de la Recherche Médicale [INSERM]) (France)

Sponsor details
INSERM U708
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Sponsor type
Research organisation

ROR
https://ror.org/02vjkv261

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (France):

Funder Name
National Institute for Prevention and Health Education (Institut National de Prévention et d'Éducation pour la Santé [INPES])

Funder Name
High Authority of Health (Haute Autorité de Santé [HAS])

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration