

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

Submission date 21/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/10/2010	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Christophe Tzourio

Contact details

Inserm U708
Hopital de la Salpetriere
Paris
France
75651
christophe.tzourio@upmc.fr

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

Hopital de la Salpetriere

Paris

France

75651

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