

Hypertension in the Very Elderly Trial

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|--|---|---|
| Submission date 18/11/2001 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 18/11/2001 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 14/11/2013 | 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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00122811

Protocol serial number
RG/97010

Study information

Scientific Title

Acronym

HYVET

Study objectives

To assess the benefits of treating very elderly patients with hypertension.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the relevant central and local ethics committees

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hypertension

Interventions

Two treatment groups:

1. Placebo
2. Indapamide Sustained Release (SR) 1.5 mg plus perindopril 2 - 4 mg if required.

Goal: diastolic blood pressure less than 80 mmHg with systolic pressure less than 150 mmHg.

The patients are followed-up both according to clinical need and every 3 months in the first year and every 6 months thereafter.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Indapamide Sustained Release (SR), perindopril

Primary outcome(s)

Stroke events (fatal and non-fatal).

Key secondary outcome(s))

1. Total mortality
2. Cardiovascular mortality
3. Cardiac mortality
4. Stroke mortality
5. Skeletal fracture

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. People 80 years old and above
2. Sustained systolic pressure 160 - 199 mmHg and diastolic (phase V) pressure 90 - 109 mmHg
3. No evidence of renal failure or co-morbidity requiring anti-hypertensive treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

Does not comply with above inclusion criteria.

Date of first enrolment

01/01/2001

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Care of the Elderly

London

United Kingdom
W12 0NN

Sponsor information

Organisation

British Heart Foundation (UK)

ROR

<https://ror.org/02wdwnk04>

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation (UK) (ref: RG/97010)

Alternative Name(s)

the_bhf, The British Heart Foundation, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Institut de Recherches Internationales Servier (France)

Results and Publications

Individual participant data (IPD) sharing plan

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 | results | 01/05/2008 | | Yes | No |
| Results article | results | 01/07/2010 | | Yes | No |
| Protocol article | main trial protocol | 01/07/2001 | | Yes | No |
| Protocol article | sub-study protocol | 19/12/2006 | | Yes | No |