# HYpertension in the Very Elderly Trial

Submission date [ ] Prospectively registered Recruitment status 18/11/2001 No longer recruiting [X] Protocol [ ] Statistical analysis plan Registration date Overall study status 18/11/2001 Completed [X] Results [ ] Individual participant data Last Edited Condition category 14/11/2013 Circulatory System

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

NCT00122811

Secondary identifying numbers

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 relevent central and local ethics committees

#### Study design

Randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

# Participant information sheet

#### 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 measure

Stroke events (fatal and non-fatal).

## Secondary outcome measures

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

## Overall study start date

01/01/2001

#### 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** 

## Age group

Senior

#### Sex

Both

# Target number of participants

2100

## 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

England

**United Kingdom** 

# Study participating centre Care of the Elderly

London United Kingdom W12 0NN

# Sponsor information

# Organisation

British Heart Foundation (UK)

## Sponsor details

14 Fitzhardinge Street London United Kingdom W1H 6DH +44 (0)20 7935 0185 research@bhf.org.uk

#### Sponsor type

Charity

#### Website

http://www.bhf.org.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**

# 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

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	main trial protocol	01/07/2001		Yes	No
Protocol article	sub-study protocol	19/12/2006		Yes	No
Results article	results	01/05/2008		Yes	No
Results article	results	01/07/2010		Yes	No