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HYVET 2: treatment of white coat hypertension in the very elderly

Submission date 09/07/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/07/2018	**Overall study status** Stopped	
Last Edited 12/03/2021	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
White coat hypertension is when a patient has raised blood pressure when they are in a clinic setting but normal blood pressure at home. At present, white coat hypertension isn't treated, but previous research has suggested that there might be some benefit to treating it in relation to conditions affecting the heart and blood vessels. This study is looking at whether it is possible to run a trial to treat white coat hypertension in older patients with blood pressure lowering drugs.

Who can participate?
Patients aged 75 and over with white coat hypertension

What does the study involve?
Participants are randomly allocated to blood pressure lowering treatment for 12 months or no treatment. There are required visits to the GP every 2 months throughout the 12-month period and participants are asked to keep a diary of any ailments that they experience during the study.

What are the possible benefits and risks of participating?
There are no specific benefits to the participant. However, research delivers wider benefits to society and this study may help to improve care for others with a similar condition in the future. Information gathered in this trial will help develop the design and delivery of the full trial.

Where is the study run from?
Brighton & Sussex Clinical Trials Unit (UK), with trial sites throughout England

When is the study starting and how long is it expected to run for?
April 2018 to April 2021

Who is funding the study?
Dunhill Medical Trust (UK)

Who is the main contact?
Dr Nicky Perry, bsctu@bsms.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Nicky Perry

Contact details
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Additional identifiers

Clinical Trials Information System (CTIS)
2017-004004-22

Protocol serial number
37147

Study information

Scientific Title
A multi-centred, open label, randomised study assessing the cardiovascular outcomes following treatment of white coat hypertension with established anti-hypertensive drugs versus standard of care in the very elderly - feasibility study

Acronym
HYVET 2

Study objectives
The HYVET 2 study is looking at whether it is possible to treat White Coat Hypertension in older patients with blood pressure lowering drugs. White Coat Hypertension is a raised blood pressure when you are in a clinic setting however, your blood pressure at home is normal. At present, White Coat Hypertension isn't treated, however, previous research has suggested that there might be some benefit to treating White Coat Hypertension in relation to conditions affecting the heart and blood vessels. We want to investigate this further.

This is a multi-centre, open-label study assessing the feasibility of conducting a randomised controlled trial to treat white coat hypertension in the very elderly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Westminster REC, 03/04/2018, ref: 18/LO/0104

Study design
Randomised; Interventional; Design type: Treatment, Drug

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
White coat hypertension

Interventions
It will entail a 1:1 randomisation of patients to a treatment arm with established antihypertensive drugs (indapamide and perindopril) and control arm (no treatment) which is current standard of care. This design will gather preliminary information on the intervention and the feasibility of conducting a full-scale randomised controlled trial. Recruitment will take place in GP surgeries.

Once potential participants have been identified through database search and mailouts or opportunistic recruitment, the participant will be invited in to consent for the trial and have a clinic blood pressure measurement. Within the next 2 weeks (+/- 7 days) the participant will return to the GP surgery for cognitive function assessments, review of past & current medical history, review of concomitant medications, another clinic blood pressure measurement, 24 hours ABPM (Ambulatory Blood Pressure Monitoring) and HBPM (Home Blood Pressure Monitoring), routine blood tests (biochemistry and haematology) and a 12 lead ECG. This will constitute the screening visits (visits 1 and 2).

Following visits 1 and 2, at Baseline (Visit 3) which is a further two weeks later +/-7 days) the particpant will be randomised to either the treatment arm or no treatment (current standard of care). An NHS prescription will then be written and given to the participant. Frailty assessments, an assessment of concomitant medications, adverse events, clinic blood pressure and other routine baseline data will be performed.

At Visits 4 and 5 (Weeks 12, 20 +/-7 days) the participant will be expected to return to the GP surgery for a clinic blood pressure measurement, assessment of adverse events and concomitant medications, HBPM, another prescription if required and a pill count of unused tablets or empty packaging.

At Visit 6 (Week 28 +/- 7 days) the participant will be required to return to the GP surgery for review of concomitant medications and adverse events, clinic blood pressure measurement, ABPM, HBPM, routine bloods (biochemistry and haematology), 12 lead ECG, prescription if required and an adherence check (pill count).

At Visits 7 and 8 (Weeks 36 and 44 +/- 7 days) the participant will be expected to come in to the GP surgery for a clinic blood pressure measurement and an assessment of concomitant medications and adverse events.

At Visit 9 (Week 52 +/- 7 days), the participant will be required to return to the GP surgery for cognitive function assessment and frailty assessments, review of concomitant medications and adverse events, clinic blood pressure measurement, HBPM, routine bloods (biochemistry and haematology), 12 lead ECG and an adherence check (pill count).

At Visit 10 (Week 60 +/- 7 days) the participant will be expected to come in to the GP surgery for a clinic blood pressure measurement, an assessment of concomitant medications and adverse events. In addition, 10 participants will be interviewed regarding their experience by members of the Patient and Public Involvement group.

Extra visits might be scheduled by the principal investigator, as appropriate, based on clinical requirement.

Follow up information on all participants will be sought after 2 years from the end of trial participation by reviewing the GP records to determine whether the participant is alive or deceased and whether they have experienced any cardiovascular outcomes.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Indapamide, perindopril

Primary outcome(s)
HYVET 2 is a feasibility study which will focus on the following outcomes:
1. The estimated proportion of eligible patients that can be recruited from initial screening by reviewing Screening Logs to determine the proportion of screened patients eligible for recruitment on an ongoing basis
2. The effectiveness of different methods of identifying/recruiting patients - search and mail out, opportunistic recruitment and posters/adverts are included in the protocol design
3. The willingness of GPs to recruit and randomise patients, assessed by getting feedback from Primary Care team and GPs directly
4. The willingness of patients to be randomised, assessed by reviewing Screening Logs to determine the proportion of screened patients eligible for recruitment on an ongoing basis
5. The recruitment rate over the trial duration and the proportion of eligible patients that provide consent on an ongoing basis
6. Adherence to the treatment protocol by performing pill counts at each visit
7. The proportion withdrawing and reason for withdrawal, assessed on an ongoing basis
8. The opportunities for PPI (patient and public involvement) in the research design and its subsequent conduct and dissemination. A lay member will sit on the TSC and a PPI panel will review patient facing documents
9. Incidence of cardiovascular events by assessing the composition of cardiovascular events on an ongoing basis
10. Ambulatory and home blood pressure (mmHg) measured on an ongoing basis

Key secondary outcome(s))
-

Completion date
22/04/2021

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients ≥75 years of age
2. Clinic sitting systolic BP ≥150 mmHg but <200 mmHg and diastolic BP <110 mmHg
3. Established diagnosis of white coat hypertension - confirmed if the mean ambulatory day time average systolic BP is <135 mmHg and diastolic BP is <85 mmHg (from at least 14 measurements) or for HBPM from BP readings twice a day for at least 5 days (ideally 7 days) at baseline
4. Not taken antihypertensive drug therapy within the last 6 months
5. Capacity to consent
6. Provision of documented informed consent
7. Ability to comply with the protocol and additional study visits and assessments

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Contraindication to the use of indapamide MR and perindopril in accordance with the summary of product characteristics
2. Regular non-steroidal anti-inflammatory drug (NSAID) use. Regular use being defined by the local GP with consideration to cardiovascular risk and blood pressure
3. Hypertensive emergency
4. Secondary hypertension
5. Postural hypotension (postural drop in systolic BP> = 20 mmHg or postural symptoms at screening)
6. Any stroke or myocardial infarction in the previous 6 months
7. Heart failure requiring treatment with drugs having an antihypertensive effect
8. Previous documented evidence of gout
9. eGFR less than 30ml/min
10. Montreal cognitive assessment score (MoCA) < 22
11. Life expectancy < 1 year due to malignancy or chronic disease

Date of first enrolment
16/07/2018

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Brockwood Medical Practice
Brockham Surgery
Tanners Meadow
Brockham
United Kingdom
RH3 7NJ

Study participating centre
Cossington House Surgery
51 Cossington Road
Canterbury
United Kingdom
CT1 3HX

Study participating centre
Furnace Green Surgery
50 The Glade
Furnace Green
Crawley
United Kingdom
RH10 6JN

Study participating centre
Henfield Medical Centre
Deer Park
Henfield
United Kingdom
BN5 9JQ

Study participating centre

Mid Sussex Healthcare
Hurstpierpoint Health Centre
Mid Sussex Health Care
Trinity Road
Hurstpierpoint
United Kingdom
BN6 9UQ

Study participating centre
Newton Place Surgery
Newton Road
Faversham
United Kingdom
ME13 8FH

Study participating centre
Park Road Surgery
143 Park Road
Camberley
United Kingdom
GU15 2NN

Study participating centre
Stone Cross Surgery
Mimram Road
Stone Cross
United Kingdom
BN24 5DZ

Study participating centre
Trinity Medical Centre
1 Goldstone Villas
Hove
United Kingdom
BN3 3AT

Study participating centre
Woodbridge Hill Surgery
1 Deerbarn Road

Guildford
United Kingdom
GU2 8YB

Study participating centre
Cleveleys Group Practice
Kelso Ave
Blackpool
United Kingdom
FY5 3LF

Study participating centre
Pendle View Medical Centre
47 Arthur St
Brierfield
Nelson
United Kingdom
BB9 5RZ

Study participating centre
Mendip Vale Medical Practice
155 Mendip Rd
Yatton
Bristol
United Kingdom
BS49 4ER

Study participating centre
West Walk Surgery
Yate West Gate Centre
21 West Walk
Yate
Bristol
United Kingdom
BS37 4AX

Study participating centre
The ColTe Partnership
76 Ambrose Ave

Colchester
United Kingdom
CO3 4LN

Study participating centre
The Bartholomew Medical Group
Goole Health Centre
Woodland Ave
Goole
United Kingdom
DN14 6RU

Study participating centre
Gilberdyke Health Centre
Thornton Dam Lane
Brough
United Kingdom
HU15 2UL

Study participating centre
Stockwell Road Surgery
21 Stockwell Road
Knaresborough
United Kingdom
HG5 0NY

Study participating centre
The Ridings Medical Group - Brough Surgery
4 Centurion Way
Brough
United Kingdom
HU15 1AY

Study participating centre
Diadem Medical Practice
2 Diadem Grove
Hull
United Kingdom
HU9 4AL

Sponsor information

Organisation
University of Sussex

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Charity

Funder Name
Dunhill Medical Trust; Grant Codes: R541/0217

Alternative Name(s)
The Dunhill Medical Trust, Dunhill Medical Trust, DunhillMedical, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date. The grant requires the data to be made available as widely as possible to maximise potential benefits; however, the plan hasn't been determined.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		16/02/2020	17/02/2021	No	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes