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Effects of an ARB on microcirculation in essential hypertension

Submission date 12/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/05/2010	**Overall study status** Completed	
Last Edited 24/01/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-005432-32

Protocol serial number
6830

Study information

Scientific Title

Effects of an angiotensin receptor antagonist candesartan versus a calcium channel blocker amlodipine on microvascular rarefaction, endothelial dysfunction, and microalbuminuria in essential hypertension

Acronym
CAMIRA

Study objectives
Many abnormalities are known to occur in the microcirculation in essential hypertension including reduction in vascular density or rarefaction. Capillary rarefaction is not confined to the skin but represents a widespread phenomenon affecting several tissues in hypertensive individuals including the myocardium, the kidneys and the brain resulting in reducing coronary blood flow reserve, and precipitating heart failure in cardiac hypertrophy. In this study we aim to investigate, in a double-blind randomised design, the effects of treating hypertension with an angiotensin receptor blocker versus a calcium antagonist on the reversibility of capillary rarefaction.

On 19/11/2013 the anticipated end date was changed from 01/10/2011 to 01/10/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London-Surrey Borders Research Ethics Committee, 19/11/2008, ref: 08/H0806/72

Study design
Single centre randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
After a 2-week single-blind placebo run-in period, patients will be randomised to 8 weeks treatment with either candesartan 8 mg once daily orally (with forced titration to 16 mg once daily orally after 2 weeks) or amlodpine 5 mg once daily orally (with forced titration to 10 mg once daily orally after 2 wks).

Study entry: single randomisation only

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Candesartan, amlodipine

Primary outcome(s)
The increase in maximal capillary density at the end of 8 weeks treatment.

Key secondary outcome(s))
1. Change in aortic augmentation index at 8 weeks
2. Change in basal capillary density at 8 weeks
3. Reduction in microalbuminuria at 8 weeks
4. Improvement in pulse wave velocity at 8 weeks

Completion date
01/10/2014

Eligibility

Key inclusion criteria
1. Male and female, aged 18 years or older
2. Uncomplicated mild-to-moderate essential hypertension, i.e., sitting diastolic blood pressure (BP) greater than or equal to 90 to less than 110 mmHg and/or systolic BP greater than or equal to 140 to less than 180 mmHg)
3. Not previously treated for their high blood pressure
4. Caucasian and light-coloured Asians only, this is due to the technical difficulty of performing capillaroscopy in dark-skinned individuals

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Malignant or accelerated hypertension
2. Serum creatinine greater than 180 µmol/L
3. Ischaemic heart disease
4. Cerebrovascular disease
5. Impaired liver functions
6. Diabetes mellitus
7. Pregnancy or risk of pregnancy

8. Lactation
9. History of alcoholism, drug abuse or other problems that are likely to invalidate the informed consent
10. Dark-skinned individuals (capillary microscopy can't be performed)

Date of first enrolment
01/02/2010

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Blood Presure Unit
Blood Presure Unit
St George's University
Cranmer Terrace
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's, University of London (UK)

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Industry

Funder Name
Takeda UK Limited (UK)

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	14/11/2017	24/01/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes