

Effects of an ARB on microcirculation in essential hypertension

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/01/2019	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

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

Primary study design

Interventional

Study design

Single centre randomised interventional treatment trial

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 amlodipine 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 $\mu\text{mol/L}$
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 Pressure Unit

Blood Pressure 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