Clinical trial results:
Effects of an Angiotensin Receptor Antagonist Candesartan versus a calcium channel blocker Amlodipine on Microvascular Rarefaction, Endothelial Dysfunction and Microalbuminuria in Essential Hypertension

Summary

EudraCT number	2008-005432-32
Trial protocol	GB
Global end of trial date	14 July 2014

Results information

Result version number	v1 (current)
This version publication date	09 November 2019
First version publication date	09 November 2019
Summary attachment (see zip file)	Effects of Candesartan versus Amlodipine on Capillary Rarefaction, Pulse Wave Velocity and Central Blood Pressure in Patients with Essential Hypertension (CAMIRA study.pdf)

Trial information

Trial identification

Sponsor protocol code	08.0113

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	St George's University of London
Sponsor organisation address	Cranmer Terrace, London, United Kingdom,
Public contact	Joint Research Office, St George's University of London, 0044 02087254986,
Scientific contact	Joint Research Office, St George's University of London, 0044 02087254986,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 January 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 July 2014
Global end of trial reached?	Yes
Global end of trial date	14 July 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effects of controlling blood pressure with candesartan 8-16 mg od versus amlodipine 5-10 mg od on microvascular capillary rarefaction in patients with mild-to-moderate essential hypertension.

Protection of trial subjects:

Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; 0
The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. There will be insufficient data collected to reach primary objective: to evaluate the effects of controlling BP with Candesartan vs Amlodipine in improving the microvascular capillary rarefaction in patients with mild to moderate essential hypertension or to answer secondary objectives of change in basal capillary density, improvement in pulse wave velocity, change in aortic augmentation index, and reduction in microalbuminuria

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 August 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 18
Worldwide total number of subjects	18
EEA total number of subjects	18

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	18
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients will attend the Blood Pressure Unit at St. George's, University of London, on 4 occasions over a period of 10 weeks. Each visit will last about 30-45 minutes. At each visit we will measure blood pressure, pulse rate and body weight.

Period 1

Period 1 title	Recruitment (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

n/a

Arms

Are arms mutually exclusive?	Yes
Arm title	arm 1

Arm description:

After 2-week single-blind placebo run-in period, patients will be randomised to 8-weeks treatment with either Candesartan 8 mg od (with forced titration to 16 mg od after 2 wks) or Amlodipine 5 mg od (with forced titration to 10 mg od after 2 wks). Blood pressure will be measured in the same arm, with an automatic oscillometric sphygmo-manometer (OMRON HEM705CP) with appropriate cuff size. Sitting and standing BP will be taken as the mean of the last 2 out of 3 readings

Arm type	Experimental
Investigational medicinal product name	Candesartan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Unknown use

Dosage and administration details:

Candesartan 8 mg capsules

Investigational medicinal product name	Amlodipine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Unknown use

Dosage and administration details:

Amlodipine 5 mg

Arm title	Arm 2

Arm description:

Placebo lactose capsules

Arm type	Placebo
Investigational medicinal product name	lactose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Unknown use

Dosage and administration details:
Placebo lactose capsules

Number of subjects in period 1	arm 1	Arm 2
Started	9	9
Completed	9	9

Baseline characteristics

End points

End points reporting groups

Reporting group title	arm 1
Reporting group description:	
After 2-week single-blind placebo run-in period, patients will be randomised to 8-weeks treatment with either Candesartan 8 mg od (with forced titration to 16 mg od after 2 wks) or Amlodipine 5 mg od (with forced titration to 10 mg od after 2 wks). Blood pressure will be measured in the same arm, with an automatic oscillometric sphygmo-manometer (OMRON HEM705CP) with appropriate cuff size. Sitting and standing BP will be taken as the mean of the last 2 out of 3 readings	
Reporting group title	Arm 2
Reporting group description:	
Placebo lactose capsules	

Primary: The increase in maximal capillary density at the end of 8 weeks treatment

End point title	The increase in maximal capillary density at the end of 8 weeks treatment
End point description:	
End point type	Primary
End point timeframe:	
8 weeks treatment	

End point values	arm 1	Arm 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	9		
Units: mm2				
number (not applicable)	0	0		

Statistical analyses

Statistical analysis title	ANOVA
Statistical analysis description:	
The study will have a power of 80% (ß= 0.20) to detect a difference of 8 in capillary density before and after treatment at a level of significance of =0.05. ANOVA for repeated measures and Student t Test would be used to compare maximal capillary density before and after treatment. A level of significance of =0.05 will be used. All measurements outlined in Section 10.3 of the protocol will be performed before randomization, at 4 weeks and at the end of the study treatment at 8 weeks. Ur	
Comparison groups	arm 1 v Arm 2

Number of subjects included in analysis	18
Analysis specification	Post-hoc
Analysis type	other
P-value	= 0.05
Method	ANOVA

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

All adverse events will be recorded in the hospital notes in the first instance.
A record of all AEs, whether related or unrelated to the treatment will also be kept in the CRF and the Sponsor's AE Log.

Assessment type	Non-systematic

Dictionary used

Dictionary name	SMPC
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 0 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: n/a

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported