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Study to evaluate the efficacy and safety of candesartan and amlodipine combination in comparison to the valsartan and amlodipine association in the treatment of arterial hypertension stages 1 and 2

Submission date	**Recruitment status**	[X] Prospectively registered
25/11/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/12/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/02/2015	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Hypertension (high blood pressure) is a chronic disease where the arterial blood pressure is persistently elevated. It is one of the major risk factors for stroke, myocardial infarction (heart attack) , heart failure and arterial aneurysm (abnormal widening or ballooning of a portion of an artery due to weakness in the wall of the blood vessel), and is a leading cause of chronic kidney failure. Effective control of arterial blood pressure (BP) significantly reduces the morbidity and mortality from cardiovascular or renal conditions. Several types of medications, called antihypertensive drugs, are available for treating hypertension. Depending on the patient condition, some of these drugs need to be combined to achieve the proper BP control. The main aim of this study is to show how well a new drug combination used to treat hypertension works to reduce BP when compared to another combination already available for the population. The new drug is a combination of candesartan plus amlodipine in the same tablet, but these drugs are available as separate tablets and may be taken together. The other combination being compared is valsartan plus amlodipine.

Who can participate?

Adults over 18 years old, male or non-fertile female, that have mild to moderate hypertension.

What does the study involve?

As a patient, you will receive only one of the two drug combinations above and will have your BP measured in the clinic and at home for comparison purposes. At home the measurement will take place during 24 hours (ambulatory blood pressure monitoring - ABPM) once before the beginning of the study and at the end of the study (approximately 3 months later). Besides BP behavior, this study will verify your acceptability and tolerance to these drugs.

What are the possible benefits and risks of participating?
The medications being studied are intended to control high blood pressure and the major expected benefit for you to enroll in the study is the treatment of your disease. However, there is no guarantee that you will personally benefit. You will not incur any costs to participate and medical treatment, tests and medication from the study will be given to you free of charge. Knowledge gained from your participation may help others with hypertension in the future. All medications may bring undesired effects. However, severe side effects are rare for these medications, like allergic reactions. The more common side effects are migraine, headache, flu-like symptoms, back pain, abdominal pain, nausea, fatigue, oedema, and ear buzz.

Where is the study run from?
This study will run only in Brazil and around 228 patients spread over 8 study centres will be enrolled. The coordinator centre is located in Rio de Janeiro city, in the Hospital Universitario Pedro Ernesto (HUPE).

When is the study starting and how long is it expected to run for?
The recruitment started in June 2012 and the study will be recruiting patients until October 2012. As the maximum study period for each participant is 15 weeks, the last patient to complete the trial is expected to be January 2013.

Who is funding the study?
This study will be entirely funded by Libbs Farmacetica Ltd.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

LB1106

Study information

Scientific Title
Open label, prospective, parallel, multicenter and randomized study to evaluate the efficacy and safety of candesartan and amlodipine combination in comparison to the valsartan and amlodipine association in the treatment of arterial hypertension stages 1 and 2

Study objectives
To show the non-inferiority of the new combination of candesartan and amlodipine compared to the valsartan and amlodipine association in the treatment of arterial hypertension stages 1 and 2

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital Universitario Pedro Ernesto (HUPE) Ethics Committee, Rio de Janeiro, Brazil, 24/11/2011

Study design
Open-label prospective parallel multicenter randomized trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Hypertension stages 1 or 2

Interventions
Patients will receive either candesartan (8, 16 or 32 mg) plus amlodipine (5 mg) or valsartan (80, 160, 320 mg) plus amlodipine (5 mg). The total duration of the intervention is 15 weeks maximum (1 week for screening, 2 weeks for wash-out and 12 weeks for drug treatment).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Amlodipine, candesartan, valsartan

Primary outcome measure
Difference between the two treatment groups with respect to the mean values of systolic blood pressure (mmHg), measured by ABPM (ambulatory blood pressure monitoring) during 24 hours before and after treatment

Secondary outcome measures
1. Difference between the two treatment groups with respect to the mean values of diastolic blood pressure (mmHg), measured by ABPM during 24 hours before and after treatment
2. Comparison of mean values of systolic and diastolic blood pressure during awake and sleep periods measured by ABPM during 24 hours before and after treatment
3. Proportion of deepers and non-deepers between the groups during sleep period before and after treatment
4. Difference in pulse pressure (24 hours and at clinic) between groups and intra-individual
5. Difference in systolic and diastolic blood pressure between the two treatment groups
6. Difference in the number of responders or controlled patients between the two treatment groups after 12 weeks of treatment

Overall study start date
01/06/2012

Completion date
31/01/2013

Eligibility

Key inclusion criteria
1. Adult patients over 18 years old from both genders
2. Informed consent form (ICF) signed by the participant
3. Patients diagnosed with hypertension stages 1 or 2, according to the definitions and orientations publicized in the VI Brazilian Arterial Hypertension Guidelines

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. Fertile women, independently of the use of contraceptive methods
2. Arterial hypertension over or equal to 180 mmHg (systolic) or 110 mmHg (diastolic) or in use of more than two anti-hypertensive drugs at the same time
3. Known hypersensitivity to study medications
4. Non-adherence to the placebo treatment during the run-in period
5. Laboratory exams collected in the screening visit considered clinically significant by the investigator
6. ECG performed during the screening visit showing ventricular arrhythmia, atrium-ventricular block of 2nd or 3rd degree, arrhythmia, tachycardia, bradycardia, or any other alteration considered clinically significant by the investigator
7. Angina pectoris Canadian Cardiovascular Society (CCS) class III or IV
8. Decompensate angina pectoris New York Heart Association (NYHA) class II or IV
9. BMI over 35 kg/m2
10. Moderate or advanced hepatic insufficiency
11. Severe or decompensate kidney insufficiency, characterized by creatinine clearance lower than 30 mL/min/1,73 m2 of corporal surface or dialyses required
12. Ongoing severe conditions, even if controlled by therapy: gastrointestinal, immunological, cardiovascular or cancer
13. Presence or history of significant edema of lower limbs (++/4+ or more)
14. Myocardial infarction, myocardial revascularization or coronary angioplasty in the last 6 months or myocardial revascularization scheduled for the next 6 months
15. Significant or decompensate cardiac valvulopathy
16. Stroke or transient ischemic attack in the last 12 months or carotid revascularization scheduled for the next 6 months
17. Uncontrolled diabetes (HbA1C over 9%)
18. History of angioneurotic oedema
19. Baseline levels of potassium over than 5 mEq/L
20. Any relevant disease that by investigator judgment may interfere in the study objectives or patients risks
21. Psychiatric disease that prevent the patient to participate in the study or cognitive disturbs (demential syndrome of any origin)

Date of first enrolment
01/06/2012

Date of final enrolment
01/10/2012

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Josef Kryss, 250
Sao Paulo

Brazil
01140-050

Sponsor information

Organisation
Libbs Farmacetica Ltda. (Brazil)

Sponsor details
Rua Josef Kryss, 250
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Brazil
01140-050

Sponsor type
Industry

Website
http://www.libbs.com.br

ROR
https://ror.org/055kp8612

Funder(s)

Funder type
Industry

Funder Name
Libbs Farmacetica Ltd. (Brazil)

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