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Comparative efficacy and safety of two formulations of ramipril combined with hydrochlorothiazide in mild to moderate hypertension

Submission date 09/08/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/09/2010	**Overall study status** Completed	
Last Edited 08/05/2013	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LB0906

Study information

Scientific Title
Open, prospective, parallel, multicentre, randomized trial to evaluate the efficacy and safety of two ramipril 5mg+ hydrochlorothiazide 25 mg formulations (Naprix D® versus Triatec D®) in the treatment of mild to moderate hypertension

Acronym
LB0906

Study objectives
This is study was designed to compare two dosage forms of combined ramipril (5mg) and hydrochlorothiazide (25mg) (capsule versus pills)

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Committee of Federal University of Sao Paulo/Sao Paulo Hospital approved on July 23rd 2010

Study design
Multicentre randomised open label prospective parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Hypertension

Interventions
Patients will be submitted to a two-week run-in phase, where their previous medication will be replaced by placebo. At the end of run-in phase, patients will be randomly allocated in one of the treatment groups, combined ramipril 5mg and hydrochlorothiazide 25mg in either pill or capsule form.
The duration of the treatment phase is 8 weeks, with two visits during this period (4 and 8 weeks).

Ambulatory blood pressure measurement (ABPM) will be performed at the end of the run-in and treatment phases.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Ramipril + hydrochlorothiazide (Naprix D® [capsule]; Triatec D® [pill])

Primary outcome measure
Reduction in mean SBP and DPB as measured by ABPM from week 2 to week 10

Secondary outcome measures
1. To assess the changes in BP during 24-h ABPM at 8 weeks
2. To assess mean change in SBP and DBP from baseline to study end at 8 weeks
3. To assess the responder rate at 8 weeks
4. To asses the mean change from study baseline in office BP following eight weeks of treatment
5. Adverse events, vital signs, laboratory tests

Overall study start date
01/12/2010

Completion date
30/07/2011

Eligibility

Key inclusion criteria
1. Both sex, adults (> 18 years)
2. Established essential hypertension, untreated or treated but uncontrolled with treatment:
2.1. Office systolic blood pressure (SBP) 160-179 mmHg and diastolic blood pressure (DBP) 100-109 mmHg for untreated patients or patients already treated with combination drug
2.2. Office SBP 140-159 mmHg and DBP 100-109 mmHg for non-controlled patients treated with monotherapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
130 patients

Key exclusion criteria
1. Women of childbearing potential
2. Known hypersensitivity to drug study or angiotensin-converting enzyme inhibitors and/or diuretics
3. No-adhesion to treatment during run-in phase
4. Abnormal and clinically significant laboratory test results
5. Abnormal and clinically relevant ECG tracing
6. Pectoris Angina
7. Decompensate Congestive Heart Failure or that requires use of antagonists of renin-angiotesin-aldosteron system
8. Obesity with BMI over 35 kg/m2
9. Advanced or moderate hepatitis insufficiency
10. Decompensate or serious renal insufficiency. Creatinine clearance above 30 mL/min/1,73 m2
11. History of any significant cardiovascular, hepatic, renal, pulmonary, hematologic, gastrointestinal, endocrine, immunologic, dermatologic, or neurologic disease
12. Recent (< 6 months) or planned coronary revascularization
13. Cerebral vascular accident in the previous twelve months
14. Non controlled diabetes mellitus
15. Any serious or relevant disease at investigator criteria

Date of first enrolment
01/12/2010

Date of final enrolment
30/07/2011

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Josef Kryss, 250
São Paulo
Brazil
01140-050

Sponsor information

Organisation
Libbs Pharmaceutical Ltd (Brazil)

Sponsor details
c/o Debora Garcia Rodrigues
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Sponsor type
Industry

ROR
https://ror.org/055kp8612

Funder(s)

Funder type
Industry

Funder Name
Libbs Pharmaceutical 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2013		Yes	No