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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 reninangiotesin-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, 250São Paulo
Brazil

01140-050

Sponsor information

Organisation

Libbs Pharmaceutical Ltd (Brazil)

ROR

https://ror.org/055kp8612

Funder(s)

Funder type

Industry

Funder Name

Libbs Pharmaceutical Ltd (Brazil)

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	01/05/2013	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes