

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 03/09/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/05/2013	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Debora Rodrigues

Contact details
Rua Josef Kryss, 250
São Paulo
Brazil
01140-050

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 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 assess 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-adherence 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-angiotensin-aldosterone 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)

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