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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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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

## Primary study design
Interventional

## Study design
Multicentre randomised open label prospective parallel group trial

## 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 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)

### 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 |