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

Recruitment status	[X] Prospectively registered
No longer recruiting	Protocol
Overall study status	Statistical analysis plan
Completed	[X] Results
Condition category Circulatory System	[] Individual participant data
	No longer recruiting  Overall study status  Completed

## 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

**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 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, 250**São Paulo Brazil

01140-050

# Sponsor information

#### Organisation

Libbs Pharmaceutical Ltd (Brazil)

#### Sponsor details

c/o Debora Garcia Rodrigues Rua Josef Kryss, 250 São Paulo - São Paulo Brazil 01140-050

#### 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