

# A clinical study to test the safety and the efficacy of a single-pill combination of 2 antihypertensive and 1 lipid-lowering drug in patients already well treated with the concomitant administration of the same three drugs on separate tablets

<b>Submission date</b> 06/12/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 02/02/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/11/2018	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration and not expected to be available in the future

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

CL3-05153-008

## Study information

**Scientific Title**

An open label study to assess the safety and efficacy of Atorvastatin/Amlodipine/Perindopril fixed-dose combination in adult patients, following four weeks of adequate treatment with atorvastatin, amlodipine and perindopril given concurrently

**Study objectives**

To assess the safety and efficacy of Atorvastatin/Amlodipine/Perindopril fixed-dose combination in adult patients.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval was obtained before recruitment of the first participants

**Study design**

Open-label randomized prospective local multicenter study

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Hypertension and dyslipidemia

**Interventions**

A total of 130 patients were included and randomized in a 1:1 ratio to one of the 2 free combination treatment dosage for 4 weeks:

1. Atorvastatin 10 mg, Amlodipine 5 mg and Perindopril 5 mg
2. Atorvastatin 20 mg, Amlodipine 5 mg and Perindopril 5 mg

At Visit 2 (Week 4):

Patients with blood pressure control were switched from their current free combination to the fixed-dose combination at the same dose levels.

Patients with uncontrolled BP were up-titrated to: Atorvastatin/Amlodipine/Perindopril FDC 20/5/10 mg

At Visit 3 (Week 8), any patient who is using either Atorvastatin/Amlodipine/Perindopril FDC 20/5/5 mg or

10/5/5 mg and having  $140 \text{ mmHg} \leq \text{SBP} < 160 \text{ mmHg}$  or  $90 \text{ mmHg} \leq \text{DBP} < 100 \text{ mmHg}$ , will also be up-titrated to Atorvastatin/Amlodipine/Perindopril 20/5/10 mg.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Atorvastatin, amlodipine, perindopril

### **Primary outcome(s)**

Safety: the number and percentage of patients reporting at least one adverse event during the usage of either Fixed Dose Combination 10/5/5 or 20/5/5; or 20/5/10 mg

W4 to W12

Efficacy: the percentage of patients who, after 8 weeks of the FDC treatment with 10/5/5 or 20/5/5 strengths, maintained the BP (office-based measurement) <140/90 mmHg and were previously treated with the free combination of atorvastatin, amlodipine, and perindopril, given concurrently at the same dose level as in the combination and controlled on the blood pressure after 4 weeks of treatment with the free combination

W4 to W12

By automatic device at office

### **Key secondary outcome(s)**

1. Safety: the number and percentage of patients reporting at least one adverse event during the usage of either free combination 10+5+5 or 20+5+5 mg
2. Inclusion to W4/premature withdrawal
3. Efficacy:
  - 3.1. Change in SBP and DBP from baseline (Week 0) to Week 12 for patients having same dosage of Atorvastatin, Amlodipine and Perindopril
  - 3.2. Percentage and absolute change in LDL-C from baseline (Week 0) to Week 12 for patients having same dosage of Atorvastatin, Amlodipine and Perindopril, and percentage of patients maintaining or achieving LDL-c target (<100 mg/dL) (all groups)
  - 3.3. The percentage of patients who, after 4 or 8 weeks of FDC treatment with 20/5/10 mg strength, achieved the BP (office-based measurement) <140/90 mmHg

### **Completion date**

13/12/2016

## **Eligibility**

### **Key inclusion criteria**

1. Confirmed inadequate BP control before study drug dispensing: for combined systolic and diastolic hypertension
2. Confirmed LDL-C value by the laboratory test performed at Selection visit
3. Patients who provide written informed consent to participate in the study
4. Outpatients of 18 years of age or above (male and female)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Known symptomatic orthostatic hypotension
2. Malignant hypertension
3. Secondary hypertension
4. Isolated diastolic hypertension
5. History of hypertension
6. Known diabetes mellitus type I or type II
7. History or current presence of lymphedema or leg edema (unilateral or bilateral) of venous origin
8. Presence of severe rhythm or conduction disorder
9. Any history of heart failure, New York Heart Association (NYHA) classification III or IV
10. Patients with contra-indications to statins, especially to Atorvastatin
11. Patients with contra-indications to calcium channel inhibitors, especially to Amlodipine
12. Patients with contra-indications to ACE inhibitors, especially to Perindopril arginine:
13. History of myopathy, familial history of hereditary muscular disorders

**Date of first enrolment**

19/04/2016

**Date of final enrolment**

14/09/2016

**Locations**

**Countries of recruitment**

Viet Nam

**Study participating centre**

**Gia Dinh People's Hospital**

Viet Nam

700000

**Study participating centre**

**Thong Nhat Hospital**

Viet Nam

700000

**Study participating centre**

**Tam Duc Heart Hospital**

Viet Nam

700000

**Study participating centre****Bach Mai Hospital**

Viet Nam

100000

**Study participating centre****National Geriatrics Hospital**

Viet Nam

100000

## Sponsor information

**Organisation**

Institut de Recherche Internationales Servier

**ROR**<https://ror.org/034e7c066>

## Funder(s)

**Funder type**

Industry

**Funder Name**

ADIR

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from <https://clinicaltrials.servier.com/> after the Marketing Authorisation has been granted.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>				No	No