# 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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
06/12/2017		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
02/02/2018		[X] Results		
Last Edited	Condition category	[] Individual participant data		
16/11/2018	Circulatory System			

## 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

Dr Hoang Hai Nguyen

#### Contact details

01 No Trang Long, Binh Thanh Dist Ho Chi Minh Viet Nam 70000

# Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

#### Secondary identifying numbers

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

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

#### 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 mmHg  $\leq$  SBP < 160 mmHg or 90 mmHg  $\leq$  DBP < 100 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 measure

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

#### Secondary outcome measures

- 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. Efficacv:
- 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

#### Overall study start date

17/07/2015

#### 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

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

### Target number of participants

130 patients randomized

#### 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

# Sponsor details

50, rue Carnot Suresnes France 92284

## Sponsor type

Industry

#### Website

http://www.servier.com/

#### **ROR**

https://ror.org/034e7c066

# Funder(s)

# Funder type

Industry

#### Funder Name

**ADIR** 

# **Results and Publications**

#### Publication and dissemination plan

Summary results will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study. The results will be published in scientific literature within 18 months after the end of the study.

## Intention to publish date

13/06/2018

# 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?
Basic results				No	No