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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 06/12/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/02/2018	**Overall study status** Completed	
Last Edited 16/11/2018	**Condition category** 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

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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 ≤ SBP < 160 mmHg or 90 mmHg ≤ 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. 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

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