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Evaluation of the clinical efficacy and safety of Perindopril / Indapamide / Amlodipine fixed-dose combination in single-pill versus free dual therapy at the same dose as the single-pill combination in patients with uncontrolled essential hypertension

Submission date 14/09/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 19/10/2012	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 18/04/2018	**Condition category** Circulatory System	[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-06593-005

Study information

Scientific Title
Evaluation of the clinical efficacy and safety of Perindopril / Indapamide / Amlodipine fixed-dose combination in single-pill versus free dual therapy at the same dose as the single-pill combination in patients with uncontrolled essential hypertension

Study objectives
To evaluate the clinical efficacy and safety of fixed-dose combination Perindopril / Indapamide / Amlodipine in single-pill versus free dual therapy in patients having an uncontrolled hypertension under ongoing treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
International multicentre randomised open-label 12-week 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
Essential hypertension

Interventions
One treatment period: Single-pill combination of Perindopril / Indapamide / Amlodipine versus free dual therapy by fixed dose combination of Perindopril / Indapamide and by Amlodipine

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Perindopril, Indapamide, Amlodipine

Primary outcome measure
1. Supine systolic blood pressure (SBP) and diastolic blood pressure (DBP): Change from baseline to last post-baseline assessment
2. Supine blood pressure normalisation

Secondary outcome measures
1. Supine and standing SBP and DBP: Change from baseline to last post-baseline assessment
2. Supine and standing blood pressure normalisation at the last post-baseline assessment for each visit measurement
3. Adverse events
4. Blood and urine biochemistry
5. Haematology
6. Vital signs and physical examination
7. 12-lead electrocardiogram

Overall study start date
01/01/2014

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Men or women of any ethnic origin > or = 18 years old
2. Uncontrolled hypertension

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Pregnancy, breastfeeding or possibility of becoming pregnant during the study
2. Hypertension known to be resistant to diuretics or ACE inhibitors
3. Secondary hypertension
4. Complicated hypertension
5. Obesity
6. History of renal disease, ventricular rhythm disorders, atrial fibrillation, atrial flutter
7. Diabetes
8. Grapefruit juice is forbidden during the study

Date of first enrolment
01/01/2014

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
France

Russian Federation

Serbia

Study participating centre
Institut de Recherche Internationales Servier
Suresnes
France
92284

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

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
Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan
Current version as of 28/03/2018:
Summary results are published in https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

IPD sharing plan: The datasets generated during and/or analysed during the current study will be available upon request from https://clinicaltrials.servier.com if a Marketing Authorisation has been granted after 1st January 2014.

Previous version as of 24/01/2018:
Publication plan:
All phases - Interventional studies ending before 01/10/2018: Summary results will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.
All phases - Interventional studies ending after 01/10/2018: Summary results and a lay summary will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.
Phase 3 only - The results will be published in scientific literature within 18 months after the end of the study.

Intention to publish date

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/ if a Marketing Authorisation has been granted after 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Results article	results	01/06/2017		Yes	No