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An efficacy and safety study comparing the fixed combination of two antihypertensive agents, indapamide and amlodipine in a single-pill, to the same drugs given separately, in patients with mild to moderate uncontrolled essential hypertension

Submission date 27/03/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 28/04/2014	**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
CL3-05520-005

Study information

Scientific Title
Safety and efficacy of fixed dose combination of Indapamide SR / Amlodipine in single-pill versus free dual therapy at the same dose over 12-week of treatment, with conditional titration based on the blood pressure control, in patients with mild to moderate uncontrolled essential hypertension: an international, multicentre, randomised, open-label study

Study objectives
To evaluate the clinical efficacy and safety of efficacy and safety study comparing the fixed combination of two antihypertensive agents, indapamide and amlodipine in a single-pill versus free dual monocomponents in patients having with mild to moderate uncontrolled essential hypertension.

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-weeks 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Essential hypertension

Interventions

Single-pill combination of Indapamide SR 1.5mg/ Amlodipine 5mg versus free dual therapy. At Week 6, the patient can be uptitrated to Indapamide SR 1.5mg/ Amlodipine 10mg versus free dual therapy. The total treatment duration is 12 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Indapamide and amlodipine

Primary outcome measure
Decrease of Office systolic blood pressure (SBP) (supine SBP value in mmHg, after 12 weeks)

Secondary outcome measures
1. SBP, diastolic blood pressure (DBP) and derivate parameters decrease after 12 weeks
2. Response to treatment and normalization of BP after 12 weeks
3. Home Blood Pressure Monitoring (HBPM) parameters efficacy after 12 weeks (HBPM device)
4. Safety of investigational drug products

Overall study start date
24/05/2014

Completion date
31/01/2015

Eligibility

Key inclusion criteria
-1. Men or women of any ethnic origin, 18 years or older
-2. Mild to moderate essential combined systolic and diastolic hypertension or isolated systolic 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. Orthostatic hypotension
3. Hypertension known to be resistant to diuretics and calcium channel inhibitors (given separately or in combination)
4. Secondary hypertension
5. Complicated hypertension
6. Diabetes mellitus type I and type II under treatment
7. Any history or known severe disease likely to interfere with the conduct of the study

Date of first enrolment
24/05/2014

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
Armenia

Russian Federation

Study participating centre
State Institution of Higher Professional Education Volgograd State Medical University of Ministry of Health and Social Development of Russian Federation
Volgograd
Russian Federation
400000

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

Sponsor details
50 rue Carnot
Suresnes
France
92284

Sponsor type
Industry

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