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	Recruitment status	[X] Prospectively registered
27/03/2014	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/04/2014	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
18/04/2018	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

Prof Sergey V. Nedogoda

#### Contact details

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## Additional identifiers

## Protocol serial number

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

### Study type(s)

Treatment

### 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(s)

Decrease of Office systolic blood pressure (SBP) (supine SBP value in mmHq, after 12 weeks)

## Key secondary outcome(s))

- 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

## 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

## Healthy volunteers allowed

No

#### Age group

Adult

## Lower age limit

18 years

#### Sex

All

## 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)

#### **ROR**

https://ror.org/034e7c066

# Funder(s)

#### Funder type

Industry

#### **Funder Name**

Institut de Recherches Internationales Servier (France)

# **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/ 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?

No