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# Observational educational study assessing efficacy of training of physicians and hypertensive patients treated with Perindopril /Indapamide single pill combination to improve antihypertensive efficacy and treatment compliance

**Submission date**
25/09/2019

**Recruitment status**
No longer recruiting

**Registration date**
18/11/2019

**Overall study status**
Completed

**Last Edited**
03/02/2020

**Condition category**
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
In clinical practice, doctors may struggle to get their patients' blood pressure controlled, and patients might not follow their recommended treatment.
The aim of this study is to assess if training of the physicians and patients with essential hypertension and use of the single-pill combination of the blood pressure controlling drugs perindopril/indapamide may improve hypertensive efficacy of treatment and treatment compliance.

Who can participate?
Patients with essential hypertension

What does the study involve?
This study collects data from patients treated with the drug perindopril arginine 10 mg /indapamide 2.5 mg (alone or in addition to other antihypertensive drugs), according to their doctor's decision. Patients are assigned into one of the three groups. In group 1, patients are followed-up by the physician according to routine clinical practice; in group 2, physicians receive training; in group 3, physicians receive training and patients are trained in self-monitoring of BP. All patients received the treatment with single pill combination perindopril/indapamide.

What are the possible benefits and risks of participating?
In this study the decision about an administration of single pill combination perindopril /indapamide was made by the physician in accordance with clinical practice. Therefore, any potential drug-related benefit or risk is linked to label for this drug.

Where is the study run from?
Department of Preventive and Emergency Cardiology, Sechenov First Moscow State Medical University

When is the study starting and how long is it expected to run for?
November 2014 to April 2016

Who is funding the study?
Servier Pharmaceuticals

Who is the main contact?
Prof. Maria Glezer
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Maria Glezer

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
IC4-06597-011-RUS

# Study information

### Scientific Title
Non-interventional educational multicenter open-label study to assess efficacy of training of the physicians and patients with essential hypertension receiving Perindopril/Indapamide single-pill

combination to achieve the target levels of blood pressure and to increase the treatment compliance

## Acronym
FORSAGE

## Study objectives
Physician and patient training and use of single-pill combination of perindopril/indapamide may improve antihypertensive efficacy and treatment compliance

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 20/06/2014, Interuniversity Ethical Committee (119002, 37, bld. 2, Gagarinsky Lane, Moscow, tel. +7 (916) 2607664), ref: 06-14

## Study design
Non-interventional educational multicenter open-label study

## Primary study design
Observational

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Arterial hypertension

## Interventions
This study collects data from patients treated with the drug perindopril arginine 10 mg /indapamide 2.5 mg (alone or in addition to other antihypertensive drugs), according to their doctor’s decision.

Patients are assigned into one of the three groups. In group 1, patients are followed-up by the physician according to routine clinical practice; in group 2, physicians receive training; in group 3, physicians receive training and patients are trained in self-monitoring of blood pressure. Patient blood pressure, as well as safety, is evaluated at baseline, then 2 weeks, 1 and 3 months after starting treatment with perindopril/indapamide single pill combination. Questionnaires are administered at baseline and end of the study.

The physician training includes the detailed consulting of the patient in problems of arterial hypertension (AH), providing of printed matter regarding the problem of AH, blood pressure (BP) control, diet in patients with AH, physical load, quitting smoking.

## Intervention Type
Other

## Primary outcome(s)
Blood pressure (mmHg) at baseline and 3-months

### Key secondary outcome(s))
1. Achievement of target levels of BP
2. Treatment compliance
3. Adverse Event/Adverse Reaction

### Completion date
18/04/2016

## Eligibility

### Key inclusion criteria
1. Adult patients (≥18 years)
2. Essential hypertension
3. BP > 150 /90 mmHg at the background of the current therapy
4. Physician’s decision to administer Perindopril/Indapamide Single-Pill Combination due to inefficacy of the previous monotherapy or combination therapy and according to the indications
5. Patient’s consent to participate in the study

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
1969

### Key exclusion criteria
1. Secondary hypertension
2. Pregnancy, breast-feeding
3. Severe cardiovascular disease (acute myocardial infarction or acute cerebrovascular accident within the last 6 months)
4. Diabetes mellitus in the stage of decompensation
5. Severe hepatic impairment
6. Renal transplantation
7. Nephrectomy or the presence of a single kidney
8. Hypokalemia or hyperkalemia
9. Chronic alcoholism, abuse of drugs
10. Contraindications for taking indapamide/perindopril arginine 2.5 mg/10mg or individual components
11. History of ACEi/indapamide/sulfonamide intolerance

12. Systemic connective tissue diseases
13. Aortic stenosis
14. Malignant neoplasm
15. Hypersensitivity reactions of any etiology
16. Presence of indapamide 1.25 mg/perindopril 5 mg or indapamide 2.5 mg/ perindopril 10 mg or free combination of its compounds (perindopril/indapamide) in a current therapy

### Date of first enrolment
01/11/2014

### Date of final enrolment
28/02/2015

## Locations

### Countries of recruitment
Russian Federation

### Study participating centre
**Department of Preventive and Emergency Cardiology, Sechenov First Moscow State Medical University**
2-4 Bolshaya Pirogovskaya str.
Moscow
Russian Federation
119991

## Sponsor information

### Organisation
JBC ‘Servier’

### ROR
https://ror.org/034e7c066

## Funder(s)

### Funder type
Industry

### Funder Name
Servier

### Alternative Name(s)
Servier Laboratories, Laboratoires Servier

### Funding Body Type
Private sector organisation

### Funding Body Subtype
For-profit companies (industry)

### Location
France

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

### IPD sharing plan summary
Stored in repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2016 | 26/09/2019 | Yes | No |
| Results article | results | 01/06/2020 | 03/02/2020 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |