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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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
Blood pressure (mmHg) at baseline and 3-months

Secondary outcome measures
1. Achievement of target levels of BP
2. Treatment compliance
3. Adverse Event/Adverse Reaction

Overall study start date
12/04/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2000

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
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Sponsor information

Organisation

JBC ‘Servier’

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Sponsor type
Industry

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

Publication and dissemination plan
We are planning the publication in the journal Cardiology and Therapy.

Intention to publish date
31/03/2020

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