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A fixed combination of amlodipine and indapamide retard in the treatment of uncontrolled arterial hypertension in people over 55

Submission date
26/09/2019

Recruitment status
No longer recruiting

Registration date
14/10/2019

Overall study status
Completed

Last Edited
07/03/2022

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
High blood pressure, or hypertension, rarely has noticeable symptoms. But if untreated, it increases the risk of serious problems such as heart attacks and strokes. The aim of this study is to assess the efficacy and tolerability of a fixed-dose combination of amlodipine and indapamide for the treatment of high blood pressure

Who can participate?
Patients with primary hypertension aged 55 years or older

What does the study involve?
Participants will be treated as usual for hypertension. In order to gather detailed information about the effects of the medication, participants will be required to attend three follow-up visits with their doctor over three months, as well as taking measurements of their blood pressure and heart rate twice per day

What are the possible benefits and risks of participating?
Care will be provided as usual and there are no additional benefits or risks to the participants from taking part in the study

Where is the study run from?
Federal State Autonomous Educational Institution of Higher Education Peoples' Friendship University of Russia (RUDN)

When is the study starting and how long is it expected to run for?
August 2017 to August 2018

Who is funding the study?
Servier, Russia

Who is the main contact?
Zhana Kobalava,
tolkachevav@mail.ru

Contact information

Type(s)
Scientific

Contact name
Ms Zhana Kobalava

ORCID ID
https://orcid.org/0000-0002-5873-1768

Contact details
Peoples' Friendship University of Russia
Mikuho-Mallaya, 6
Moscow
Russian Federation
117198
+7 (499) 134-65-91
tolkachevav@mail.ru

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IC4-05520-047-RUS

Study information

Scientific Title
Evaluation of the efficacy and tolerability of a fixed-dose combination of amlodipine and indapamide in patients older than 55 years

Acronym
ARBALET

Study objectives
To evaluate the efficacy and tolerability of a fixed-dose combination of amlodipine and indapamide in patients older than 55 years with grade 1-2 HT, not achieving BP control on the previous therapy or not receiving antihypertensive therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was not required (under Russian law) for this observational study

Study design
Multicenter observational open-label uncontrolled program

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
The aim of the study is to observe the efficacy and safety of treatment with amlodipine /indapamide fixed-dose combination (FDC) ARIFAM in outpatients with hypertension (HT) aged over 55 years.

The ARIFAM dose was chosen by the doctor from two available dosages of amlodipine /indapamide FDC: 5/1.5 mg and 10/1.5 mg. During the 3-month follow-up period starting from the inclusion visit, the patient visited the doctor three times: after 2 weeks, 1 month and 3 months.

At all visits, blood pressure (BP) and heart rate (HR) were measured in the sitting and standing positions, and well being was assessed using a VAS. At the follow-up visits patients were also asked about adverse events. In addition, at each visit, the diary of BP self-monitoring, which the patient had to complete throughout 7 days prior to visiting the doctor, was analyzed.

ARIFAM was prescribed in accordance with the instruction for use of the drug after the patient had signed the informed consent form. The drug could be prescribed not only to patients with a failure of hypertension control on the previous therapy, but also to those in whom the doctor decided to replace the effective free combination of these drugs with a FDC.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Amlodipine and indapamide

Primary outcome(s)
Blood pressure and heart rate assessed in the seated and standing positions during consultations with the doctor will be measured in addition to self measurements of BP and HR taken twice daily by participants throughout the three months.

Key secondary outcome(s))
Subjective evaluation of the effectiveness of therapy by the doctor and patient assessed by interview during follow-up visits (after 2 weeks, 1 month and 3 months)

Completion date
22/08/2018

Eligibility

Key inclusion criteria
1. Age 55 years or older
2. Diagnosis of essential (primary) hypertension
3. Suboptimal efficacy of the previous antihypertensive therapy, with clinical SBP 140-179 mm Hg, OR untreated grade 1-2 HT with clinical SBP 140-179 mm Hg, in patients requiring therapy with amlodipine and indapamide.
4. Pulse pressure 60 mm Hg or higher
5. Doctor's decision to prescribe ARIFAM in line with indications.
6. Patient’s informed consent to participate in the program
7. Absence of contraindications to the prescription of ARIFAM, stated in the instruction for medical use of the medicinal product.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
2217

Key exclusion criteria
1. Office BP ≥180/110 mm Hg on the top of treatment (at V1 visit) or ≥200/110 mm Hg if untreated
2. Resistant HT (use of at least 3 antihypertensive drug classes, one of which is diuretics, at maximal doses)
3. Known or suspected symptomatic orthostatic hypotension
4. History of myocardial infarction or cerebrovascular accident within the past 6 months
5. Unstable angina within the past 6 months
6. CHF of class III-IV NYHA
7. Type 1 diabetes mellitus or decompensated type 2 diabetes mellitus
8. Any serious decompensated concomitant diseases requiring regular medical therapy
9. Inability to understand the nature of the program and follow the recommendations
10. Contraindications or known intolerance to diuretics or calcium channel blockers (indapamide and amlodipine)

11. Patient who could/would not stop drinking grapefruit juice during the study (interaction with amlodipine)
12. Current participation in another study or within the preceding 30 days (or a longer period in accordance with local regulations)

Date of first enrolment
26/08/2017

Date of final enrolment
22/08/2018

Locations

Countries of recruitment
Russian Federation

Study participating centre
Federal State Autonomous Educational Institution of Higher Education Peoples' Friendship University of Russia (RUDN)
Mikuha-Maklaya, 6
Moscow
Russian Federation
117198

Sponsor information

Organisation
Servier

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Servier Russia

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	21/12/2018	12/11/2020	Yes	No
Results article		04/03/2022	07/03/2022	Yes	No