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Viacoram® - focus on blood pressure target

Submission date 11/09/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/10/2015	**Overall study status** Completed	
Last Edited 31/10/2019	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Arterial hypertension (high blood pressure) can cause premature death. In Germany, about 30% of women and 33% of men aged between 18-79 have hypertension. In adults aged between 70-79, some 75% of people of both sexes have the condition. Based on the public importance of the disease, a timely return to a normal blood pressure should always be the aim. If the recommended initial non-pharmacological (drug) measures (for example, lifestyle changes) are not successful, a drug treatment should be started. Viacoram® is a single-pill combination of two drugs, amlodipine and perindopril, both used for treatment of arterial hypertension. It is used for the treatment of adult patients with arterial hypertension. The aim of this observational study is to gain information on the use of Viacoram® in outpatients with hypertension. This study will focus on the change of the blood pressure, time to achieve normal blood pressure, change in other treatments the patients may be taking as well as whether they keep taking the drug (therapy adherence) and an assessment of general tolerability.

Who can participate?
Adult outpatients with arterial hypertension that have been recommended treatment with Viacoram®.

What does the study involve?
All patients in the trial involved in the study are treated with Viacoram®. They are asked to come to three follow up visits after 1, 2 and 3 months. During these visits a routine practice investigation is carried out and a case report form regarding blood pressure, other diseases the patient is suffering from and what other medications they are taking is filled out by the treating physician. The patients are asked to fill out the patient questionnaire to therapy adherence at the first and the last visit.

What are the possible benefits and risks of participating?
The patients have no particular benefits or risks of participating in this observational study. The treatment given to the patient corresponds to the standard medical routine and is completely independent of the study as the study is strictly non-interventional. Patients are free to withdraw from the study at any time without giving a particular reason.

Where is the study run from?
Study will be carried out by approximately 1000 general practitioners across Germany.

When is study starting and how long is it expected to run for?
September 2015 to April 2016

Who is funding the study?
Servier Deutschland, GmbH (Germany)

Contact information

Type(s)
Public

Contact name
Dr Peter Martinka

Contact details
Servier Deutschland GmbH
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Germany
80687

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IC4-05985-161-DEU

Study information

Scientific Title
Viacoram® - focus on blood pressure target. An open single-arm non-interventional observational study in hypertensive outpatients treated with Viacoram® in Germany.

Acronym
VIACORAM-BPT

Study objectives
Aim of this non-interventional study is to gain information on the use of Viacoram® in hypertensive outpatients in line with the marketing authorization under the conditions of daily practice in Germany. Special focus of the study is the change in the blood pressure (office, ABPM, central BP parameters), time to achieve the BP target, change in the concomitant treatments and therapy adherence as well as assessment of general tolerability.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Freiburg Ethics Committee International ("Freiburger Ethik Komission Internation), 27/07/2015, ref: 015/1441

Study design
Prospective, open, multicentre, single-arm, observational, non-interventional study.

Primary study design
Observational

Secondary study design
Longitudinal 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
Essential hypertension

Interventions
This is strictly a non-interventional observational study. Only interventions in line with and not exceeding the standard medical routine are allowed. All patients involved in the study will be treated with Viacoram® under the circumstance that the decision about the treatment was done prior to the study initiation. After the inclusion the patients will be asked to come to three follow up visits after 1, 2 and 3 months. During these visits a routine practice investigation will be carried out and a case report form regarding blood pressure, concomitant diseases and co-medications will be filled out by the treating physician. The patients will be asked to fill out the patient questionnaire to therapy adherence at the first and the last visit.

Intervention Type
Other

Primary outcome measure
Office blood pressure measured within the daily medical routine at inclusion, after approx. 1 month, 2 months and at study final examination after approx. 3 months.

Secondary outcome measures
1. Ambulatory BP monitoring only in measured as part of the medical routine at inclusion, after approx. 1 month, 2 months and at study final examination after approx. 3 months
2. Central BP parameters only in measured as part of the medical routine at inclusion, after approx. 1 month, 2 months and at study final examination after approx. 3 months
3. Assessment of therapy adherence measured by means of the Hill-Bone-Scale

Overall study start date
21/09/2015

Completion date
30/04/2016

Eligibility

Key inclusion criteria
Adult patients with essential hypertension with currently not controlled blood pressure eligible for the treatment with Viacoram® for whom the treatment decision was done prior to study inclusion.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3000

Total final enrolment
1814

Key exclusion criteria
N/A

Date of first enrolment
21/09/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Germany

Study participating centre
General practitioners
Germany
-

Sponsor information

Organisation
Servier Deutschland GmbH

Sponsor details
Elsenheimerstr. 53
München
Germany
80687

Sponsor type
Industry

Website
www.servier.de

ROR
https://ror.org/05wk4ae67

Funder(s)

Funder type
Industry

Funder Name
Servier Deutschland GmbH (Germany)

Results and Publications

Publication and dissemination plan
The whole study report including all results will be published according to the German drug act on the website of the German regulatory authority (BfArM) within one year after completion of the study. An abstract will be submitted to the Congress of the German Hypertension League in December 2016. This will contain the main results regarding the BP decrease and time to achieve BP goal as well as patient compliance data.

Intention to publish date
30/04/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2018	31/10/2019	Yes	No