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Triveram in patients with hypertension and concomitant primary hypercholesterolemia or mixed hyperlipidemia

Submission date
11/04/2016

Recruitment status
No longer recruiting

Registration date
30/06/2016

Overall study status
Completed

Last Edited
09/02/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Cardiovascular (heart) diseases present are the most frequent reason for premature death, accounting for almost 4 million deaths in Europe per year. High blood pressure (hypertension) and high levels of blood lipids (fats) are two of the most commonly co-occurring cardiovascular risk factors. More than 64% of patients with high blood pressure also have high blood fat levels, and conversely, almost 47% of patients with high blood fat also have high blood pressure. These two factors together cause an accelerated damage to blood vessels. Treatment with a combination of the blood pressure lowering drugs perindopril and amlodipine with a lipid-lowering agent atorvastatin has been found to better protect against cardiovascular events such as heart attacks compared to a similar combination of betablocker, diuretic and atorvastatin. Triveram® is a combination of the above mentioned agents, atorvastatin, perindopril and amlodipine, in a single tablet. It is used to treat high blood pressure and/or stable coronary artery disease (a condition where the blood supply to the heart is reduced or blocked) in adults who also suffer from elevated cholesterol levels (primary hypercholesterolemia) or elevated cholesterol and fat (triglyceride) levels at the same time (combined or mixed hyperlipidemia). Triveram® is intended for patients already on treatment with atorvastatin, perindopril and amlodipine as single tablets. The aim of this study is to gather information on the use of Triveram® in adult outpatients suffering the above mentioned diseases in daily practice, with a focus on changes in blood pressure, lipid parameters and other treatments, as well as treatment adherence, pill burden and treatment satisfaction.

Who can participate?
Adult outpatients with arterial hypertension and elevated cholesterol levels or elevated cholesterol and fat levels at the same time.

What does the study involve?
All patients involved in the study are treated with Triveram® under the circumstance that the decision about the treatment was made before the start of the study. The patients are asked to come to two follow-up visits after 1 and 4 months. During these visits a routine practice investigation is carried out and a form will be filled out by the treating physician regarding blood

pressure, blood lipids (fats), and other diseases and medications. The patients are asked to fill out the patient questionnaire about treatment adherence, pill burden and treatment satisfaction at the first and the last visit.

What are the possible benefits and risks of participating?
There are no particular benefits or risks of participating in this study. The treatment given to the patient is the standard medical routine treatment and is completely independent of the study. Patients are free to withdraw from the study at any time without giving a particular reason.

Where is the study run from?
It is planned that the study will be carried out by about 700 general practitioners and cardiologists across Germany. There is no lead center.

When is the study starting and how long is it expected to run for?
April 2016 to May 2017

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

Who is the main contact?
Dr Bettina Weger
bettina.weger@servier.com

Contact information

Type(s)
Scientific

Contact name
Dr Bettina Weger

Contact details
Servier Deutschland GmbH
Elsenheimerstr. 53
München
Germany
80687
+49 (0)89 57095488
bettina.weger@servier.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IC4-05153-179-DEU

Study information

Scientific Title
TRIVERAM-PRACTICE: an open, multi-center, single-arm, non-interventional, observational study in hypertensive outpatients with concomitant primary hypercholesterolemia or mixed hyperlipidemia treated with Triveram in Germany

Acronym
TRIVERAM-PRACTICE

Study objectives
In previous clinical studies the free combination of Perindopril, Amlodipine and Atorvastatin showed good efficacy in treatment of patients with essential hypertension and concomitant hypercholesterolemia. Data are lacking on the practical use of a new fixed-dose combination of atorvastatin, perindopril and amlodipine - Triveram® - in daily practice in patients with hypertension and concomitant primary hypercholesterolemia or mixed hyperlipidemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Freiburg Ethics Committee International, 29/02/2016, ref: 016/1161

Study design
Prospective open multicenter 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Essential hypertension with concomitant primary hypercholesterolemia or mixed hyperlipidemia

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 two

follow-up visits after 1 and 4 months. During these visits a routine practice investigation will be carried out and a case report form regarding blood pressure, lipid parameters, 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, pill burden and therapy satisfaction at the first and the last visit.

Intervention Type
Other

Primary outcome measure
Office blood pressure and lipid parameters measured within the daily medical routine at inclusion, after approx. 1 month and at study final examination after approx. 4 months.

Secondary outcome measures
1. Ambulatory blood pressure monitoring only in measured as part of the medical routine at inclusion, after approx. 1 month and at study final examination after approx. 4 months
2. Home blood pressure at inclusion, after approx. 1 month and at study final examination after approx. 4 months
3. Assessment of therapy adherence measured by means of the Hill-Bone-Scale at inclusion and at study final examination after approx. 4 months
4. Assessment of pill burden and therapy satisfaction at inclusion and at study final examination after approx. 4 months

Overall study start date
04/04/2016

Completion date
31/05/2017

Eligibility

Key inclusion criteria
Adult patients with essential hypertension and concomitant hypercholesterolemia or mixed hyperlipidemia eligible for the treatment with Triveram® in line with the marketing authorization for whom the treatment decision was done prior to study inclusion.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1350

Total final enrolment
483

Key exclusion criteria
N/A

Date of first enrolment
04/04/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Germany

Study participating centre
700 cardiologists and general practicioners
Germany
-

Sponsor information

Organisation
Servier Deutschland GmbH (Germany)

Sponsor details
Elsenheimerstr. 53
München
Germany
80687

Sponsor type
Industry

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 2017. This will contain the main results regarding the blood pressure, blood lipids as well as patient adherence, pill burden and treatment satisfaction data.

Added 19/01/2021
Currently there are no journal publications planned but the final study report is available at the BfArM Website (website of the national health authority): https://awbdb.bfarm.de/ords/f?p=101:25:::NO::P25_AWB_ID:92549

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Bettina Weger (bettina.weger@servier.com). The data is available upon request from now until 2025. Data will be shared only for scientific purposes in electronic format. Informed consent was obtained from all participants. Individual data are anonymized.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			19/01/2021	No	No