

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

<b>Submission date</b> 11/04/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/02/2021	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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

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## 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 practitioners

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](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?
<a href="#">Basic results</a>			19/01/2021	No	No