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A survey evaluating blood pressure control and treatment adherence in the general hypertensive population with concomitant hypercholesterolemia or stable coronary artery disease

Submission date
12/07/2017

Recruitment status
No longer recruiting

Registration date
13/09/2017

Overall study status
Completed

Last Edited
15/04/2019

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Hypertension (high blood pressure) and hypercholesterolemia (high blood cholesterol) are two of the most commonly co-occurring cardiovascular (heart disease) risk factors, with 338 million patients worldwide with both conditions. Reductions in blood pressure or total cholesterol have been shown to reduce the risk of cardiovascular disease. However, blood pressure control in these patients is difficult, with a major contributing factor being poor adherence to treatment, which has been shown to be significantly improved by the use of single-pill combinations. The aim of this study is to assess blood pressure control in hypertensive patients with hypercholesterolemia or stable coronary artery disease.

Who can participate?
Hypertensive outpatients aged over 18 with hypercholesterolemia or stable coronary artery disease

What does the study involve?
Participants' medical history, other diseases and medications are assessed using a questionnaire. Treatment adherence is assessed by asking about their current use of antihypertensive medication and statins.

What are the possible benefits and risks of participating?
Participation in the study will enable a better understanding of how patients with high blood pressure are characterized, treated and managed. No additional investigations or treatments are required in order to collect the data, therefore there is no risk to the participants.

Where is the study run from?
University Hospital Leipzig (Germany)

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

Who is funding the study?
Servier International (France)

Who is the main contact?
1. Ms Andrea Korzinek
2. Prof. Ulrich Laufs

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DIM-05153-001

Study information

Scientific Title
A survey evaluating blood pressure control and treatment adherence in the general hypertensive population with concomitant hypercholesterolemia or stable coronary artery disease: an observational cross-sectional study

Study objectives
The primary objective is to evaluate blood pressure control in hypertensive patients with concomitant hypercholesterolemia or stable coronary artery disease (stable CAD).

The secondary objective is to evaluate treatment adherence using the Morisky Medication Adherence Scale-8 (MMAS-8) self-assessment questionnaire and number of antihypertensive pills prescribed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission at the Medical Association of the Saarland (Germany), 25/01/2017, ref: ID: 307 /16

Study design
Single-visit multicentric non-interventional cross-sectional survey

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Hypertensive outpatients with concomitant hypercholesterolemia or stable coronary artery disease

Interventions
Medical history, concomitant diseases and medication will be documented by a questionnaire. Treatment adherence will be assessed by self-reported current use of antihypertensive medication and statins using the MMAS-8.

Intervention Type
Other

Primary outcome measure
Blood pressure control, evaluated using office blood pressure values and blood pressure targets corresponding to the latest ESH/ESC Guidelines for the management of arterial hypertension 2013. One visit per patient (snapshot, no follow-up data)

Secondary outcome measures
Treatment adherence and number of antihypertensive pills prescribed, evaluated using the Morisky Medication Adherence Scale-8 (MMAS-8) self-assessment questionnaire. One visit per patient (snapshot, no follow-up data)

Overall study start date
01/09/2016

Completion date
01/12/2017

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Confirmed (in medical records) diagnosis of hypertension
3. Confirmed (in medical records) diagnosis of hypercholesterolemia or stable coronary artery disease
4. Prescription of ≥1 antihypertensive medication
5. Prescription of a statin
6. Signed consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3500

Total final enrolment
3188

Key exclusion criteria
Patients hospitalized for cardiovascular diseases in the last 3 months (including revascularization)

Date of first enrolment

15/03/2017

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Leipzig
Germany
04103

Sponsor information

Organisation
Servier International

Sponsor details
35 rue de Verdun
Suresnes
France
92285

Sponsor type
Industry

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Servier International

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. The data required for the statistical evaluation of this survey will be transmitted in pseudonymised (encrypted) form to Servier Deutschland GmbH and to a data processing office commissioned by Servier Deutschland GmbH, called PHARMALOG Institut für klinische Forschung GmbH (Neumarkter Strasse 18, 81673 Munich) as well as in anonymized form to Servier International 35 rue de Verdun, 92285 Suresnes cedex, and they will be stored at these three locations for a maximum of 10 years. This will take place in accordance with the data protection regulations in force in Germany.

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	18/12/2018	15/04/2019	Yes	No