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Evaluation of the control of risk factors to develop ATHEROsclerosis in patients treated by general practioners in Belgium and Luxembourg

Submission date 05/01/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/01/2018	**Overall study status** Completed	
Last Edited 06/10/2022	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Hypertension and hypercholesterolemia are two of the most commonly co-occurring cardiovascular risk factors. Hypertension is the leading cardiovascular risk factor contributing to global mortality and nearly half of the hypertensive patients are also diagnosed with hypercholesterolemia. Co-existence of hypertension and hypercholesterolemia has more than an additive adverse impact on the vascular endothelium, resulting in increased atherosclerosis and a subsequent increase in coronary events. Unfortunately, concomitant hypertension and hypercholesterolemia are very difficult to control. This is in part due to poor adherence to medication in individuals at high cardiovascular risk and in patients with coronary artery disease, resulting in worse outcomes and higher healthcare costs. Evidence shows that single-pill combination therapy decreases the risk of medication non-adherence compared with free combination therapy and improved adherence in turn has been shown to significantly improve CV outcomes. In Belgium, there are few epidemiological data on current treatment of hypertensive patients with concomitant hypercholesterolemia or stable coronary artery disease and the way in which general practitioners apply the treatment recommendations in current clinical practice. With this study we try to bridge this gap of knowledge by evaluating in daily clinical practice at the general practitioner level the control of risk factors to develop atherosclerosis in patients treated with at least one antihypertensive agent and a statin.

Who can participate?
Adults treated with at least one antihypertensive agent and one statin and seen by a general practitioner in Belgium.

What does the study involve?
General practitioners records information of patient on a routine consultation about their background, current medical treatment, blood pressure and LDL-c levels.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved to those taking part in the study.

Where is the study run from?
Servier BeNeLux (Belgium)

When is the study starting and how long is it expected to run for?
November 2017 to January 2019

Who is funding the study?
Servier BeNeLux (Belgium)

Who is the main contact?
Mr. Bregt Van Nieuwenhuyse

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ATHERO IC4-05153-024-BEL

Study information

Scientific Title
Cross-sectional study evaluating the control of risk factors to develop ATHEROsclerosis in the general population of Belgium and Luxembourg treated with at least one antihypertensive agent and a statin.

Acronym
ATHERO

Study objectives
The aim of this study is to evaluate in daily clinical practice at the general practitioner level in Belgium and Luxembourg the control of risk factors that develop atherosclerosis in patients treated with at least one antihypertensive agent and a statin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Due to the observational nature of this study, it does not require ethics approval according to the European directive and Belgian law.

Study design
Cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Treatment

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
Hypertension

Interventions
All participants attend an appointment to see their general practitioner, who is asked to record the following information:
1. Number of the patient in the study (1 to 15)
2. Age, sex, weight and height of the patient
3. Presence of concomitant cardiovascular risk factors/co-morbidities (diabetes, prior CV events, renal disease, heart failure, peripheral vascular disease, smoking, at risk age, familial predisposition)
4. Systolic/diastolic blood pressure (mmHg)
5. LDL-c and total cholesterol values (mg/dl) (measured within previous 12 months)
6. Physician-reported attainment of LDL target and BP control according to international guidelines
7. Antihypertensive treatment before consultation (name, therapeutic class and daily dose)
8. Cholesterol lowering treatment before consultation (name, therapeutic class and daily dose)
9. Motivation to use single pill combinations before treatment of hypertension and dyslipidemia

Due to the transversal nature of the study, no follow-up of the patients is performed.

Intervention Type
Other

Primary outcome measure
1. Systolic and diastolic blood pressure values is measured using according to the general practitioners' standard operating procedure during consultation
2. LDL-c and total cholesterol is noted based on medical records at time of consultation

Secondary outcome measures
1. Number of antihypertensive and cholesterol lowering drugs taken before consultation is measured using medical records
2. Cardiovascular risk of on-treatment patients in Belgium and Luxembourg is measured using medical records and patient anamnesis during consultation
3. Judged BP control and cholesterol control is measured by asking the general practitioners' clinical evaluation during consultation
4. Judgement of the suitability of the patient for single pill combinations & motivation is measured using by asking the general practitioners' clinical evaluation during consultation
5. Types of antihypertensive and lipid lowering treatment used in Belgium and Luxembourg is measured using medical records

Overall study start date
15/11/2017

Completion date
31/01/2019

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 drug
5. Prescription of a statin

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

4725

Total final enrolment
2337

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

Date of first enrolment
01/02/2018

Date of final enrolment
19/01/2019

Locations

Countries of recruitment
Belgium

Luxembourg

Study participating centre
Servier Benelux
Internationalelaan 57
Anderlecht
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1070

Sponsor information

Organisation
Servier Benelux

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Sponsor type
Industry

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Servier Benelux

Results and Publications

Publication and dissemination plan
After completion of the study a scientific report will be written and data will be send out for publication.

Intention to publish date
01/09/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from bregt.vannieuwenuyse@servier.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			06/10/2022	No	No