

Evaluation of the motivation and key drivers of general practitioners in Belgium and Luxembourg to SIMPLIFY or intensify antihypertensive treatment in uncontrolled hypertensive patients

Submission date 28/03/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/04/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/08/2022	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Hypertension (high blood pressure) is a long term medical condition in which the pressure in the arteries is higher than it should be. It is major risk factor for cardiovascular disease (disease of the heart and blood vessels), which can lead to heart attack and stroke. Although there is a wide range of medications available that help lower blood pressure, many patient's still have poorly controlled blood pressure. In addition, for effective blood pressure control, many patients need to take more than one blood pressure medication. Having to take a lot of pills increases the risk that patients may not stick to their treatment program, leading to poor blood pressure control. The aim of this study is to complete a large-scale survey to investigate the motivation and key drivers in the therapeutic decision making process to improve (simplify or intensify) blood pressure medication treatment in patients with poorly controlled high blood pressure at general practitioners in Belgium and Luxembourg.

Who can participate?

Adults with high blood pressure who are taking at least one blood pressure medication, are seen by a general practitioner in Belgium or Luxembourg.

What does the study involve?

Participants attend an appointment with their GP, who records information about their background, current medical treatment, and blood pressure. Based on this information the GP decides whether any changes are needed in the current medical treatment. The information is then collated in order to find out whether there are any patterns in a GPs decision to simplify or intensify blood pressure medication treatment.

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?
January 2017 to September 2017

Who is funding the study?
Servier BeLux (Belgium)

Who is the main contact?
Mr Bregt Van Nieuwenhuyse

Contact information

Type(s)
Scientific

Contact name
Mr Bregt Van Nieuwenhuyse

Contact details
Servier Benelux
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VI 17/01/20/01

Study information

Scientific Title
Cross-sectional survey evaluating the motivation and key drivers of general practitioners to SIMPLIFY or intensify antihypertensive treatment in the general uncontrolled hypertensive population treated with at least one antihypertensive agent in Belgium and Luxembourg

Acronym
SIMPLIFY

Study objectives

The aim of this study is to evaluate the motivation and key drivers of general practitioners to simplify or intensify antihypertensive treatment in uncontrolled hypertensive patients already treated with at least one antihypertensive drug.

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. Nonetheless, the study has been approved by pharma. be (Bureau Des Visas Études Scientifiques Décision, 31/01/2017, ref: 17/01/20/01)

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 below 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. Age, sex, weight and height of the patient
2. number of years previously being treated with antihypertensive drug(s)
3. Presence of comorbidities (specify: diabetes, renal insufficiency, prior CV complications, heart failure, arrhythmia, renal insufficiency, dyslipidemia or other)
4. Systolic and diastolic blood pressure
5. compliance to antihypertensive treatment
6. Medical treatment before consultation /
 - 6.1 need to change current medical treatment? (yes/no)
 - 6.2 if 6.1 yes: Medical treatment after consultation
6. If the patient has been prescribed a single pill combination, for which reason? (better compliance, better prognosis, cheaper, better control of blood pressure, simpler for the patient?)

The information collected by the GP is data collected routinely by the GP during a standard consultation for hypertension. No other data than data needed for the patient file is collected.

Based on the collected patient information and the performed medical decision making, it will be calculated which variables are the main drivers for simplification or intensification of the antihypertensive treatment.

Intervention Type

Other

Primary outcome measure

Change in antihypertensive treatment (yes or no) in relation to blood pressure values (controlled or uncontrolled blood pressure) is assessed using information collected at the GP appointment.

Secondary outcome measures

1. Change in antihypertensive treatment (yes or no) in relation to therapeutic compliance is assessed using information collected at the GP appointment
2. Change in antihypertensive treatment (yes or no) in relation to total pill burden is assessed using information collected at the GP appointment
3. Change in antihypertensive treatment (yes or no) in relation to antihypertensive pill burden is assessed using information collected at the GP appointment
4. Change in antihypertensive treatment (yes or no) in relation to type of antihypertensive treatment is assessed using information collected at the GP appointment
5. Change in antihypertensive treatment (yes or no) in relation to comorbidities/CV risk is assessed using information collected at the GP appointment
6. Change in antihypertensive treatment (yes or no) in relation to patient demographics is assessed using information collected at the GP appointment

Overall study start date

20/01/2017

Completion date

25/09/2017

Eligibility

Key inclusion criteria

1. Uncontrolled hypertensive patients
2. Treated with at least one antihypertensive drug
3. Consulting a general practitioner
4. Aged 18 years and over

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

5175

Total final enrolment

1852

Key exclusion criteria

Secondary hypertension.

Date of first enrolment

16/03/2017

Date of final enrolment

08/06/2017

Locations

Countries of recruitment

Belgium

Luxembourg

Study participating centre**Servier BeNeLux**

Internationalelaan 57

Anderlecht

Belgium

1070

Sponsor information

Organisation

Servier Benelux

Sponsor details

Internationalelaan 57

Anderlecht

Belgium

1070

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

25/09/2018

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.vannieuwenhuyse@servier.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		11/12/2018	11/12/2018	No	No
Results article		05/04/2021	06/04/2021	Yes	No
Protocol file			23/08/2022	No	No
Protocol file			23/08/2022	No	No