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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

Registration date
05/04/2017

Overall study status
Completed

Last Edited
23/08/2022

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 vlood 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
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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 insuffisciency, prior CV complications, heart failure, arritmia, 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
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1070

Sponsor information

Organisation
Servier Benelux

Sponsor details
Internationalelaan 57
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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
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