ISRCTN14491942 https://doi.org/10.1186/ISRCTN14491942

Evaluation of achieved blood pressure control with more than one antihypertensive drug in patients treated by general practitioners in Belgium

Submission date
13/04/2016

Recruitment status
No longer recruiting

Registration date
14/04/2016

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Hypertension is a long-term medical condition in which the pressure of blood travelling through the arteries is too high. This puts increased strain on the heart which, if left untreated, can lead to increased risk of heart attack or stroke. It is extremely common and is a major cause of death and disease worldwide, however many cases remain undiagnosed and treatment is not as effective as it could be. General practitioners play an important role in the early diagnosis and treatment of high blood pressure. In general, patients are treated with a combination of different drugs, as using a single drug is only effective in a limited number of patients. If initial treatment with two drugs fails then the current guidelines recommend increasing the dosage of these drugs, switching to two different drugs or adding a third drug. If treatment with three drugs is needed, the guidelines favour the use of fixed-dose or single-pill combinations, because reducing multiple drug treatment to one tablet daily helps improve the chance of patients always remembering to take their medication. The aim of this study is to complete a large-scale survey to investigate how well blood pressure is controlled in hypertensive patients who are being treated with more than one blood pressure medication.

Who can participate?
All hypertensive patients who are taking more than one blood pressure medication and are seen by the general practitioner cabinet in Belgium.

What does the study involve?
Participants attend appointments with their GP, who records their age and gender, current medical treatment, and blood pressure. The information is then collated in order to evaluate the blood pressure control of the participants.

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?
Erasme Hospital Free University of Brussels (Belgium)

When is the study starting and how long is it expected to run for?
October 2014 to September 2016

Who is funding the study?
Servier BeLux (Belgium)

Who is the main contact?
1. Ms Valerie Pauwels (public)
2. Mr Bregt Van Nieuwenhuyse (scientific)

Contact information

Type(s)
Public

Contact name
Ms Valerie Pauwels

Contact details
Servier BeLux
Internationalelaan 57
Anderlecht
Belgium
1070

Type(s)
Scientific

Contact name
Mr Bregt Van Nieuwenhuyse

Contact details
Servier BeLux
Internationalelaan 57
Anderlecht
Belgium
1070

Additional identifiers

Protocol serial number
Visa Pharma.be: VI 14/10/06/01

Study information

Scientific Title

Cross-sectional survey evaluating blood pressure target ACHIEVEment in the Belgian general hypertensive population treated with multiple anti-hypertensive agents according to the treatment received

Acronym
ACHIEVE

Study objectives
The aim of this study is to evaluate the blood pressure control of hypertensive patients treated with multiple anti-hypertensive drugs according to the type of treatment received (number of drugs & free, fixed or mixed type of association).

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) on 16/10/2014 (dossier 14/10/06/01)

Primary study design
Observational

Study design
Cross-sectional observational study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypertension

Interventions
Participants attend an appointment to see their general practitioner, who is asked to record the following information:
1. Age and sex of the patient
2. Presence of comorbidities (specify: diabetes, prior CV complications, renal insufficiency, or other)
3. Systolic and diastolic blood pressure
4. Is the patient controlled: Yes or No
5. Current antihypertensive treatment (free associations and/or fixed associations)
6. If the patients is not treated with a fixed association, would you switch them on: fixed bitherapy: Yes or No? // fixe tritherapy: Yes or No?
6.1. If Yes, for which reason?: better compliance?/Better blood pressure control?/better prognosis?/other?

Intervention Type
Other

Primary outcome(s)

Systolic and diastolic blood pressure is measured according to clinical practice during cabinet visit

Key secondary outcome(s)
1. Isolated systolic hypertension is calculated based on blood pressure measurement according to clinical practice during cabinet visit
2. Judged blood pressure control is written down in CRF by treating general practitioner during cabinet visit
3. Blood pressure control according to ESH/ESC guidelines is evaluated in comparison with blood pressure measurement according to clinical practice during cabinet visit
4. Number of antihypertensive drugs is written down in CRF by treating general practitioner during cabinet visit
5. Type of antihypertensive associations used (free, fixed or mixed) is written down in CRF by treating general practitioner during cabinet visit

Completion date
14/09/2016

Eligibility

Key inclusion criteria
All hypertensive patients treated with more than one antihypertensive drug consulting a general practitioner

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
No exclusion criteria

Date of first enrolment
19/01/2015

Date of final enrolment
14/02/2016

Locations

Countries of recruitment
Belgium

Study participating centre
Erasme Hospital Free University of Brussels (Hôpital Erasme Université Libre de Bruxelles)
Route de Lennik 808
Brussel
Belgium
1070

Sponsor information

Organisation
Servier BeLux

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Servier BeLux

Results and Publications

Individual participant data (IPD) sharing plan

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	01/11/2018		Yes	No
Dataset		01/11/2018	19/05/2023	No	No
Protocol (other)		01/11/2018	19/05/2023	No	No