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An observational study of patients with apparent resistant hypertension in Belgium

Submission date 03/08/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/08/2020	**Overall study status** Completed	
Last Edited 19/09/2023	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Hypertension, or high blood pressure, is the leading cardiovascular risk factor contributing to global deaths. Hypertension can usually be effectively treated with lifestyle changes and medication. Lowering elevated blood pressure reduces the risk of major cardiovascular events such as heart attack or stroke.

Hypertension is defined as resistant to treatment when, in patients who adhere to treatment, the recommended treatment strategy fails to lower blood pressure under 140/90 mmHg, when measured at home or during normal daily life (ambulatory). Sometimes there will be true resistance to treatment of hypertension, where no treatment will lower blood pressure, however, in some cases, there are reasons for high blood pressure to appear resistant to treatment when it is in fact treatable. According to the European guidelines on hypertension management, the main causes of this apparent resistant hypertension are:
1. Poor adherence to prescribed medicines
2. The white-coat phenomenon, where, in consultation with healthcare staff, blood pressure is raised, but blood pressure is controlled at home
3. Poor blood pressure measurement technique, for example, the use of cuffs that are too small relative to the arm circumference

Evidence shows that single-pill combination therapy (when there are multiple molecules in one pill) decreases the risk of patients not adhering to medication compared with free combination therapy (where multiple pills are taken). Improved adherence has been shown to significantly improve heart and blood vessel health outcomes.

In Belgium, no data currently exists on the prevalence of apparent versus true resistant hypertension. Many patients may be referred to specialized services for resistant hypertension while having apparent treatment-resistant hypertension. To evaluate whether treatment-resistant hypertension is being overdiagnosed in patients, this study will investigate the prevalence of true resistant hypertension in patients referred to specialized hospital centers for “resistant hypertension”. The trial will consider individual patient health, non-adherence, the white coat phenomenon, and inadequate dosing or irrational combinations of blood pressure-lowering drugs.

Who can participate?
Adults referred to specialized hospital centre for apparent resistant (non-controlled) hypertension

What does the study involve?
General practitioners will record information of patients in a routine consultation about their background, current medical treatment and blood pressure.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for those taking part in the study, as participants will receive standard care.

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

When is the study starting and how long is it expected to run for?
From September 2019 to June 2021

Who is funding the study?
Servier BeNeLux (Belgium)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
TREAT IC4-06593-044-BEL

Study information

Scientific Title
Multi-center Cross-sectional TReatment Evaluation of Apparent resistant hyperTension in Belgium (TREAT)

Acronym
TREAT

Study objectives
The aim of this study is to evaluate in daily clinical practice in Belgium the extent of pseudo-resistant and true resistant hypertension in patients referred to specialized hospital centers for apparent resistant hypertension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Due to the observational nature of this study, ethics approval is not required 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
No participant information sheet available

Health condition(s) or problem(s) studied
Resistant 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 cardiovascular events, renal disease, heart failure, peripheral vascular disease, smoking, at risk age, familial predisposition)
4. Systolic/diastolic blood pressure (mmHg)
5. Antihypertensive treatment before consultation (name, therapeutic class and daily dose)
6. Self-reported adherence (determined based on the Hill-Bone Scale)

The 9-item Hill-Bone Scale has broad application across various chronic diseases and conditions for self-assessment of medication adherence. It is a useful tool for conditions like hypertension, diabetes, COPD, and stroke. These brief scales provide a simple method for clinicians in various settings to assess patients' self-reported adherence and to plan appropriate interventions. Each can be self-administered or interviewer-administered in less than 5 minutes, thus making each clinically useful. The Hill Bone scale is proposed to the treating physician, without the obligation of use, to assess therapeutic adherence to blood pressure-lowering treatments. The Hill-Bone scale consists of 9 four-point Likert-type items (1 = none of the time, 2 = some of the time, 3 = most of the time, and 4 = all the time). The total scores on this subscale range from 9 to 36 with higher scores reflecting poorer adherence to antihypertensive drug therapy.

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 measured according to the general practitioners' standard operating procedure during the consultation

Secondary outcome measures
1. Number of antihypertensive drugs taken prior to the consultation assessed from medical records during the consultation
2. Cardiovascular risk of on-treatment patients in Belgium measured using medical records and patient anamnesis during the consultation
3. Types of antihypertensive used in Belgium assessed from medical records during the consultation
4. Self-reported adherence to treatment measured using the Hill-Bone Scale during the consultation

Overall study start date
01/09/2019

Completion date
01/06/2021

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Referred to specialized hospital centre for apparent resistant (non-controlled) hypertension
3. Office (consultation) systolic blood pressure ≥140 mmHg and/or office diastolic blood pressure ≥90 mmHg
4. Treated with ≥3 antihypertensive drugs

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
390

Total final enrolment
232

Key exclusion criteria
1. Patients referred to specialized hospital centre with suspicion of secondary hypertension

Date of first enrolment
01/10/2020

Date of final enrolment
01/04/2021

Locations

Countries of recruitment
Belgium

Study participating centre
Servier Benelux
Boulevard International 57
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Sponsor information

Organisation
Servier Benelux

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Sponsor type
Industry

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
01/01/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

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