

# An observational study of patients with apparent resistant hypertension in Belgium

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>03/08/2020   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>26/08/2020 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>19/09/2023       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## 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?

Mr. Bregt Van Nieuwenhuyse

bregt.vannieuwenhuyse@servier.com

## Contact information

**Type(s)**

Scientific

**Contact name**

Mr Bregt Van Nieuwenhuyse

**Contact details**

Boulevard international 57

Anderlecht

Belgium

1070

+32 (0)2 529 43 48

bregt.vannieuwenhuyse@servier.com

## Additional identifiers

**Protocol serial number**

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

## Study type(s)

Treatment

## 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(s)**

1. Systolic and diastolic blood pressure values measured according to the general practitioners' standard operating procedure during the consultation

### **Key secondary outcome(s)**

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

### **Completion date**

01/06/2021

## **Eligibility**

### **Key inclusion criteria**

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

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Total final enrolment**

**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

Anderlecht

Belgium

1070

**Sponsor information**

**Organisation**

Servier Benelux

**Funder(s)**

**Funder type**

Industry

**Funder Name**

Servier Benelux

**Results and Publications**

**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? |
|-------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol file</a> |         |              | 06/10/2022 | No             | No              |