

# Study evaluating uncontrolled systolic blood pressure in middle-aged and older patients with high blood pressure

<b>Submission date</b> 21/07/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/08/2020	<b>Condition category</b> 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. This puts increased strain on the heart which, if left untreated, can lead to increased risk of heart attack or stroke. Antihypertensive treatments, such as medications to reduce blood pressure, are effective at lowering blood pressure and therefore stroke risk. This study aims to look at the blood pressure of middle-aged and older patients with high blood pressure and to see if there is a link with stroke risk and whether they are taking blood-pressure controlling medication.

### Who can participate?

Adults aged 50 and over (60 and over in Columbia) who have high blood pressure.

### What does the study involve?

Participants are reviewed as part of their usual clinical care, and once selected to participate in the study, are asked to sign an informed consent form. They then attend a single clinic visit at which their medical history, personal information, information about any medication they are taking to lower blood pressure and their blood pressure is taken. This information is then used to calculate the 5-year and 10-year risk of stroke for each patient using the Stroke Riskometer™ application.

### What are the possible benefits and risks of participating?

There are no direct benefits or risks involved with participating in this study.

### Where is the study run from?

The study is run from Serdia Pharmaceuticals Pvt. Ltd. (India) and takes place in 176 health centres in India, 10 in Malaysia and 32 in Columbia.

### When is the study starting and how long is it expected to run for?

October 2015 to December 2016

Who is funding the study?  
Servier International (France)

Who is the main contact?  
Stéphane DUBOIS, Pharm.D.  
(updated 07/08/2020, previously: Dr Harpreet Lhoste)

## Contact information

**Type(s)**  
Public

**Contact name**  
Miss Nathalie Barbet

**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
DIM-05520-001

## Study information

**Scientific Title**  
SYSTUP: Study evaluating uncontrolled SYSTolic blood pressUre in middle-aged and older Patients with hypertension, in relation to stroke risk and current antihypertensive treatment

**Acronym**  
SYSTUP

**Study objectives**  
The aim of this study is to assess the level of raised systolic blood pressure in an older population, and to correlate this with stroke risk and antihypertensive treatment.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

1. India: Lancelot Independent Ethics Committee, 23/12/2015
2. Malaysia: Medical Research Ethics Committee, 02/08/2017
3. Colombia: no Ethics approval required

## **Study design**

Multi-centre multi-country cross-sectional study

## **Primary study design**

Observational

## **Secondary study design**

Cross sectional study

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Hypertension (particularly a raised systolic blood pressure) and stroke risk

## **Interventions**

If a potential participant fulfills the inclusion criteria, the investigator will present the main objectives of this study to them and will provide them with an information sheet. If the patient agrees to the recording of completely anonymous medical data concerning themselves, they will sign the participant consent form and be included into the study. Participants attend a single study visit at which the following data will be recorded using the case report form:

1. Demographic data (age)
2. Blood pressure reading during the visit with confirmation that systolic blood pressure is raised (blood pressure should be measured via the ESH guidelines using an auscultatory or oscillometric semiautomatic sphygmomanometer; allow the patient to sit for 3-5 minutes before taking measurements, take blood pressure from each arm and use the arm with the higher value as the reference, document the highest of at least two BP measurements taken from the reference arm at least 1-2 mins apart whilst in the sitting position)
3. Stroke risk factors (ethnicity, waist and hip circumference, diabetes, smoking, previous cardiovascular disease, diet, alcohol, stress, family history of cardiovascular disease);
4. Stroke risk score using Stroke Riskometer™, where possible (this can be downloaded from Google Play [Android] or App Store [Apple], further details on [www.strokeriskometer.com](http://www.strokeriskometer.com))
5. Antihypertensive treatment taken at the time of visit

## **Intervention Type**

Other

## **Primary outcome measure**

1. Systolic blood pressure is measured using an auscultatory or oscillometric semiautomatic sphygmomanometer at the study visit

2. Stroke risk is determined using Stroke Riskometer™ at the study visit
3. Antihypertensive use is determined through qualitative interviews at the study visit

**Secondary outcome measures**

No secondary outcomes

**Overall study start date**

06/10/2015

**Completion date**

30/06/2018

## Eligibility

**Key inclusion criteria**

1. Age  $\geq 50$  years\* ( $\geq 60$  years in Columbia)
2. Confirmed (in medical records) diagnosis of hypertension
3. Elevated systolic blood pressure ( $\geq 140$  mm Hg)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

Participants = approx. 4242 total (3945 india, 208 Colombia, 89 Malaysia)

**Key exclusion criteria**

Conditions that prevent participation in the study, such as the inability to complete the participant consent form.

**Date of first enrolment**

01/03/2016

**Date of final enrolment**

30/07/2016

## Locations

**Countries of recruitment**

Colombia

India

Malaysia

**Study participating centre****Serdia Pharmaceuticals (India) Pvt. Ltd.**

Serdia House

off Dr. S. S. Rao Road,

Parel

Mumbai

India

400 012

**Study participating centre****Laboratorios Servier de Colombia SAS**

Edificio 98-28

Transversal 19A# 98-28

Bogotá

Bogotá

Colombia

-

**Study participating centre****Servier Malaysia SDN. BHD.**

Suite 1005, 10th Floor

Wisma Hamzah-Kwong Hing

Kuala Lumpur

Malaysia

50100

## **Sponsor information**

**Organisation**

Servier International

**Sponsor details**

50 rue Carnot

Suresnes

Ile de France

France

92284

**Sponsor type**

Industry

**ROR**

<https://ror.org/034e7c066>

## Funder(s)

### Funder type

Industry

### Funder Name

Servier International

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration.

### Intention to publish date

31/12/2017

### 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?
<a href="#">Basic results</a>		06/08/2020	06/08/2020	No	No