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

Submission date
21/07/2016

Recruitment status
No longer recruiting

Registration date
08/09/2016

Overall study status
Completed

Last Edited
07/08/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] 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. 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
Global Medical Affairs - GMA Cardiology
35 rue Verdun
Suresnes Cedex
France
92284

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)
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 ≥50 years* (*≥60 years in Columbia)
2. Confirmed (in medical records) diagnosis of hypertension
3. Elevated systolic blood pressure (≥ 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?
Basic results		06/08/2020	06/08/2020	No	No