

Strategies for improving blood pressure control in Africa

Submission date 24/05/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/05/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Hypertension (high blood pressure) is the leading cause of disability and death in the world. It is a particular problem in Africa, where genetic causes of salt and water retention make hypertension more common, and make blood pressure control more difficult. In many cases, the exact cause of hypertension is not known, which can make finding the most appropriate treatment more difficult. By testing the blood for specific chemicals - renin (a kidney enzyme) and aldosterone (a hormone produced by the adrenal glands, located on top of the kidney) - it is possible to identify which treatments would be most effective based on the actual cause of the hypertension. The aim of this study is to look at the effectiveness of individualized therapy based on the physiological cause of the hypertension as determined from the plasma renin and aldosterone testing.

Who can participate?

Adult patients with resistant hypertension (blood pressure above 160/90 despite three medications) who are attending one of the three hypertension clinics participating in the study.

What does the study involve?

Patients are randomly allocated to one of two groups. Those in the first group continue to receive usual care according to the consensus guidelines of the country in which the clinic is located. Those in the second group take part in a new strategy of care based on finding the underlying physiological process that is causing the high blood pressure. This is done by taking a sample of blood and measuring levels of renin, and aldosterone. The results of these tests are then analysed and used to choose the most appropriate therapy. Participants in both groups are followed up after one year to find out if their blood pressure control has improved.

What are the possible benefits and risks of participating?

It is anticipated that the patients who take part in the new strategy will benefit from better blood pressure control. There are no notable risks involved with taking part in this study.

Where is the study run from?

1. Ladoke Akintola University of Technology Teaching Hospital (Nigeria)
2. Groote Schuur Hospital (South Africa)
3. Nakuru County Referral Hospital (Kenya)

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

September 2013 to June 2016

Who is funding the study?

Grand Challenges Canada (Canada)

Who is the main contact?

Dr. J. David Spence
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

01

Study information

Scientific Title

Physiologically individualized therapy for resistant hypertension in Africa

Study objectives

Individualized therapy for resistant hypertension will improve blood pressure control compared to usual therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Human Research Ethics Board of Western University, 20/08/2013 (renewal date: 10/11/2014), ref: 103876
2. University of Cape Town Faculty of Health Sciences Human Research Ethics Committee, 04/04/2013, ref: 169/2013
3. Ethical Committee Ladoke Akintola University of Technology Teaching Hospital, 20/06/2013, ref: LTH/OGB/Ec/2013/003
4. Egerton University Research Ethics Board, 22/07/2013, ref: EUIDVRE/009

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Resistant hypertension

Interventions

On the first study visit, participants have blood samples taken for measurement of plasma renin and aldosterone using kits provided by Diagnostics Biochem Canada Inc, and a sample of blood to be sent for DNA extraction and Sanger sequencing to identify genetic factors that may cause salt and water retention.

Patients are randomized using random numbers generated in SPSS, to either the usual care group (in which the plasma renin and aldosterone results are blinded to the physician and the patient) or the physiologically individualized treatment group, in which the plasma renin and aldosterone levels are used to choose the most appropriate therapy. The algorithm used to interpret the plasma renin and aldosterone levels and choose appropriate therapy was described in 2012 (Spence JD. Lessons from Africa: the importance of measuring plasma renin and aldosterone in resistant hypertension. *Can J Cardiol.* 2012 May;28(3):254-7. PMID: 22289470).

Participants in both groups are followed up for one year in the hypertension clinic, with visits scheduled according to the usual routine in each clinic.

Intervention Type

Drug

Phase

Phase III

Primary outcome(s)

Blood pressure control, defined as a systolic pressure <140 mmHg and Diastolic Control is defined as a diastolic pressure <90, is measured using an automated blood pressure device at baseline and one year.

Key secondary outcome(s)

Nucleotide polymorphisms (SNPs) found in the candidate genes are measured using sanger sequencing at baseline in the intervention group only.

Completion date

22/05/2016

Eligibility**Key inclusion criteria**

1. Blood pressure greater than 160 systolic or 90 diastolic
2. Currently on three medications including a diuretic
3. Attending the hypertension clinic at the study site
4. Aged 18 and over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Renal failure
2. Congestive heart failure
3. Patients with a serious health condition that would limit life expectancy to less than one year

Date of first enrolment

03/07/2014

Date of final enrolment

03/07/2015

Locations**Countries of recruitment**

Kenya

Nigeria

South Africa

Study participating centre**Ladoke Akintola University of Technology Teaching Hospital**

Cardiology Clinic

Department of Medicine

General area

Ogbomoso-Ilorin Road

Ogbomoso

Nigeria

202061

Study participating centre**Groote Schuur Hospital**

Hypertension Clinic

Cape Town

South Africa

7925

Study participating centre**Nakuru County Referral Hospital**

Medical Outpatient Department

Nakuru Town

Kenya

20100

Sponsor information**Organisation**

Grand Challenges Canada

ROR<https://ror.org/02snbhr24>**Funder(s)****Funder type**

Government

Funder Name

Grand Challenges Canada

Alternative Name(s)

Grands Défis Canada, gchallenges, Grand Challenges Canada / Grands Défis Canada, grandchallengescanada, GCC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017		Yes	No