

# Plasma renin test guided drug treatment algorithm for correcting different subtypes of hypertension in treated but uncontrolled patients

<b>Submission date</b> 30/12/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/05/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

High blood pressure (hypertension), if untreated, increases the risk of serious problems such as heart attacks and strokes. Medication remains the mainstay of treatment, and its benefits are gained mostly from lowering blood pressure; however, the control rates of blood pressure remain unsatisfactory worldwide, which is at least in part due to a lack of methods to select an efficient antihypertensive drug(s) for a individual patient from the numerous drugs available. To this end, an approach for selecting anti-hypertensive drugs called the renin test guided therapeutic (RTGT) algorithm has been demonstrated to work better than standard care in patients with treated but uncontrolled hypertension. The aim of this study is to examine whether the blood pressure lowering ability of this approach varies according to the different types of hypertension, namely isolated diastolic hypertension (IDH), systolic diastolic hypertension (SDH) and isolated systolic hypertension (ISH).

### Who can participate?

Patients aged 18 or over with hypertension who are not currently taking anti-hypertensive medication

### What does the study involve?

In the first visit, the patient's blood pressure is recorded and they are classified into one of the three hypertension types. They are then prescribed with one of two antihypertensive drugs depending on their blood pressure. At the second visit scheduled 2 weeks later, patients whose blood pressure reached the target level are excluded from the study to ensure that the patients being further tested are those with treated but uncontrolled hypertension with their original hypertension types. A blood sample is taken for the plasma renin activity (PRA) test. The patients are then randomly allocated to be treated with antihypertensive drugs according to the RTGT algorithm or senior general cardiologist's care (SGCC), where the drugs are chosen based

on the physician's personal judgment unaware of the patient's PRA values. The changes in blood pressure levels and antihypertensive drugs between the second and the last visit are compared between the RTGT and SGCC groups and between the three types of hypertension.

What are the possible benefits and risks of participating?

Patients in the RTGT group may benefit from lower blood pressure and/or may need fewer anti-hypertensive drugs to control their blood pressure compared with the SGCC group receiving drug treatment as usual. The only anticipated risk for the participants is the possibility that their blood pressure remains high or rises during the study leading to heart complications, but the chances are minor because the antihypertensive drug(s) are continuously given during the study.

Where is the study run from?

Second Hospital of Hebei Medical University (China)

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

November 2009 to June 2012

Who is funding the study?

Hebei Science and Technology Agency (China)

Who is the main contact?

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## Contact information

### Type(s)

Scientific

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

10276101D

## **Study information**

### **Scientific Title**

Plasma renin test guided drug treatment algorithm for correcting different subtypes of hypertension in treated but uncontrolled patients: a randomized trial

### **Study objectives**

Laragh et al have recently demonstrated in a randomized clinical trial that the renin test guided therapeutic (RTGT) algorithm, an approach they developed based on physiological analyses of pathogenesis of hypertension for selecting antihypertensive drugs to lower blood pressure (BP), worked better than clinical hypertension specialists care (CHSC) in treated but uncontrolled hypertensive patients. It remains unclear, however, whether RTGT works equally well in lowering BP in the patients with different hypertension subtypes, namely, isolated diastolic hypertension (IDH), systolic diastolic hypertension (SDH) and isolated systolic hypertension (ISH), which are commonly believed to be different in physiological abnormalities contributing to elevated BP, such that SDH arises from concomitant increase in both central arterial stiffness and peripheral vascular resistance, ISH reflects increased central arterial stiffness alone, and IDH is a consequence of an increase only in peripheral vascular resistance. The present study is, therefore, to examine a hypothesis that there might be different responses to RTGT between the patients with different hypertension subtypes.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Research Ethics Committee, Second Hospital of Hebei Medical University, November 2009, ref: 09109

### **Study design**

Randomized non-blinded open labelled controlled clinical trial

### **Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

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

Hypertension, treated but uncontrolled

**Interventions**

1. RTGT: The antihypertensive drugs were chosen based on the renin test guided therapeutic (RTGT) algorithm.
2. Senior General Cardiologists Care (SGCC): The antihypertensive drugs were chosen based on the physicians personal judgment unaware of patients plasma renin activity (PRA) values.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Primary outcome measure**

Differences in change in BPs between RTGT and SGCC groups with the three hypertension subtypes, respectively, and between the three hypertension subtypes within RTGT group.

**Secondary outcome measures**

Differences in change in the antihypertensive drug number between RTGT and SGCC groups with the three hypertension subtypes, respectively, and between the three hypertension subtypes within RTGT group.

**Overall study start date**

02/11/2009

**Completion date**

30/06/2012

**Eligibility**

**Key inclusion criteria**

1. Established hypertensive patients
2. 18 years or older

3. Male or female of any race or ethnicity
4. Have never had anti-hypertensive medication
5. Have had anti-hypertensive medication but not for at least two weeks

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

180

**Key exclusion criteria**

1. Any comorbidities requiring the medications that interferes with blood pressure (BP) levels (e.g. non-steroidal anti-inflammatory drugs with the exception of aspirin)
2. Any contraindications to any types of antihypertensive drug applied in this study (e.g. asthma)
3. Any situations leading to poor adherence to the study protocol (e.g. mental illness or instability in BP levels e.g. cardiovascular neurosis)
4. Home BP 135/85 mmHg
5. History of white-coat hypertension
6. Serum creatinine >2.5 mg/dl

**Date of first enrolment**

02/11/2009

**Date of final enrolment**

30/06/2012

**Locations****Countries of recruitment**

China

**Study participating centre**

Second Hospital of Hebei Medical University

Shijiazhuang

China

050000

**Sponsor information**

**Organisation**

Second Hospital of Hebei Medical University (China)

**Sponsor details**

215 Heping Road  
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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/015ycqv20>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

Hebei Science and Technology Agency (China) (ref: 10276101D)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration