ISRCTN15531697 https://doi.org/10.1186/ISRCTN15531697

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

Submission date
30/12/2011

Recruitment status
No longer recruiting

Registration date
24/01/2012

Overall study status
Completed

Last Edited
26/05/2017

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
1. Prof. Zejun Tian
2. Prof. Yuming Hao
haoyuming@medmail.com.cn

Contact information

Type(s)
Scientific

Contact name
Prof Zejun Tian

Contact details
215 Hepingxi Road
Department of Cardiology
Second Hospital of Hebei Medical University
Hebei Province
Shijiazhuang
China
050000

Type(s)
Scientific

Contact name
Prof Yuming Hao

Contact details
Department of Cardiology
Second Hospital of Hebei Medical University

No. 215, Hepingxi Road
Shijiazhuang
China
050000
-
haoyuming@medmail.com.cn

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 lowing 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
Hebei Province
Shijiazhuang
China
050000

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