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Program to optimize the treatment compliance and blood pressure control in hypertensive patients in real cardiologist's practice

Submission date
29/01/2013

Recruitment status
No longer recruiting

Registration date
23/05/2013

Overall study status
Completed

Last Edited
29/05/2013

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?
Despite best treatment for high blood pressure, blood pressure (BP) control is achieved in less than one third of the patients. The main reason is the low adherence of patients to the treatment and lack of awareness about high blood pressure and its consequences. The need to take many pills, several times a day, for a long time and possible side effects of drugs significantly reduce the number of patients who are treated continuously. Less effective treatment is also due to lack of simple step-by-step administration of a particular combination of drugs (Perindopril and Amlodipine) that can be effective in decreasing blood pressure, with low probability of side effects and the possibility of a single dose daily. Effective treatment can be reached when doctors make home visits to measure patients blood pressure. Self-monitoring of blood pressure by the patients between doctor visits also promotes adherence to treatment. The objective of this study is to see how good such a stepwise administration of treatment is along with BP monitoring at home and educating patients to keep to treatment.

Who can participate?
Patients with blood pressure more than 160/100mmHg if they have not been treated or more than 140/90mmHg if they have received therapy with one, two or three antihypertensive drugs can participate in the study.

What does the study involve?
The study includes patients aged 35 to 70, with high blood pressure and who are in the outpatient treatment. Patients visit the doctor for over 6 months. In the first visit, the doctor evaluates the patients demographic information, medical history, risk factors, information about the treatment conducted, blood pressure, heart rate and adherence to treatment by questionnaire. In addition, every participant of the study receives recommendations to alter their lifestyle and instructions for measuring blood pressure at home. The doctor conducts screening and decides on the inclusion of the patient in the trial, If included, their current treatment is stopped depending on the condition of the patient. The doctor chooses the drug combination (perindopril/amlodipine) according to initial blood pressure and presence of other diseases, where the patient may require an increased dose. In the second visit, doctor changes

the therapy according to the results achieved by previous treatment. The effectiveness of the treatment using this combination of drugs is assessed using various parameters.

What are the possible benefits and risks of participating?
There is no immediate direct benefit to those taking part. All participants receive an additional teaching material regarding the procedure to be performed. Information obtained from this study may be helpful in future. By taking part in this study there are no risks of physical injury or harm to the participants.

Where is the study run from?
The PERFECT-BP study has been set up by the Cardiovascular Surgeons Association (Ukraine) and Kiev City Therapeutic Society (Ukraine).

When is study starting and how long is it expected to run for?
The study started in March 2012 and will run for one year or until the required number of patients have been recruited and evaluated

Who is funding the study?
Cardiovascular Surgeons Association and Kiev City therapeutic Society. Kiev, Ukraine

Who is the main contact
Professor Amosova Ekateryna
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Contact information

Type(s)
Scientific

Contact name
Prof Ekaterina Amosova

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Open clinical program implemented to optimize efficacy of blood pressure control and patient's compliance in every day out-patient cardiological practice

Acronym
PERFECT-BP

Study objectives
Evaluate efficacy and tolerability of unified step-by-step antihypertensive therapy based on fixed combination of perindopril arginine/amlodipine with added indapamide retard in combination with correct home blood pressure monitoring and the education program for hypertensive patients in out-patient cardiological practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ukraine Central Ethics Committee, 02.03.2012, ref: no. 5.12 310/KE

Study design
Single center prospective open study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Arterial hypertension

Interventions
If the patient previously was not treated, he is administered fixed combination of perindopril /amlodipine (Bi-Prestarium) in dose of 5/5 mg, 5/10 or 10/5 mg once per day. The doctor chooses the dose according to baseline blood pressure and comorbidity in patient who may require increased doses of Perindopril and Amlodipine. If the patient was treated before the doctor prescribes therapy according to its own judgment based on the algorithm of treatment that is detailed below. Prescription of drugs on each successive step is possible only after the

prescription of treatment on the previous steps.
Step 1: prescribing Bi-Prestarium one tablet per day
Step 2: increasing dose of Bi-Prestarium to maximum tolerated
Step 3: prescribing indapamide retard (Arifon Retard) once per day
Step 4: prescribing Spironolactone 25 mg twice per day
Step 5: prescribing Moxonidine in dose of 0.2 mg to 0.6 mg per day or Doxazosin 4-8 mg per day
At the first visit the patient is prescribed also aspirin and statin on medical indications.
Second and subsequent visit: the doctor changes the therapy according to the results achieved by previous treatment by its decision based on the treatment algorithm that was discussed above.
Prescribing of drugs on each successive step is possible only after reaching the maximum tolerated dose of Bi-Prestarium and having ordered the treatment on previous steps.
Overall treatment for one patient is 12 months.
In the course of trial the deviation from the established dosage regimen scheme is not allowed.
In the case where in the opinion of a physician there is a need to deviate from the appointed regimen scheme the patient should be excluded from the trial and substituted with another one.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Perindopril , Amlodipine, indapamide

Primary outcome measure
1. Percentage of the patients who had achieved BP (less than 140/90 mm Hg) and for diabetes pts . BP<135/85 mm Hg
2. Percentage of the patients who had achieved home BP (less than 135/85 mm Hg)

Secondary outcome measures
1.Compare the achievement of target office blood pressure with a frequency achievement of target home BP, according to an independent measurement of blood pressure
2. Frequency of achieving BP control (<135/80 mm Hg.) for self-measurement of home blood pressure
3. Dynamics of office SBP and DBP reduction
4. Assessment of tolerability: dynamics of the patient's side effect
5. Assessment of adherence: Dynamics of the patient`s compliance - patient compliance assessed by questionnaire test X. Girerd

Sub study
1.Dynamic of average daytime and nighttime SBP and DBP assessed with ABPM
2. Dynamics of central systolic blood pressure and central pulse pressure dynamics
3. Dynamic of echocardiography indexes
4. Dynamics of pulse wave velocity

Overall study start date
10/03/2012

Completion date

01/04/2013

Eligibility

Key inclusion criteria
1. Patient with arterial hypertension
2. Men and women aged 35-70 years
3. Not yet treated with BP>160/100 <200/120 mm Hg
4. Uncontrolled with monotherapy (SBP>140/90 <200/120 mm Hg)
5. Uncontrolled with combination of 2 antihypertensive (SBP>140/90 <200/120 mm Hg)
6. Uncontrolled with combination of 3 antihypertensive (SBP>140/90 <200/120 mm Hg)
*patients should stop previous treatment at the day of inclusion and be switched to fixed combination of perindopril arginine/amlodipine B-blocker allowed for CAD patients but dose of B-blockers should be stable during all period of study.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
520

Key exclusion criteria
1. Cerebrovascular events within 3 last month of anamnesis
2. Myocardial infarction within 6 last of anamnesis
3. Valvular heart disease
4. Uncontrolled arrhythmias
5. Pregnant or lactating woman
6. COPD during exasperation
7. Contraindications linked to ACEi or CCBs, or its intolerance (including allergic reaction linked to these drugs)
8. II types diabetes (fasting glycaemia>7 mmol/l)
9. Renal failure (GFR<60 ml/min)
10. Renal artery stenosis, hyperthyroidism
11. Oncology disease
12. Mental disease, alcoholism,
13. Liver failure (ALT, AST)
14. Heart failure (NYHA II and more)
15. BP>200/120 mm Hg

Date of first enrolment
10/03/2012

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
Ukraine

Study participating centre
13 Shevchenko boulevard, Bogomolets National Medical University, Department of Internal Medicine #2
Kiev
Ukraine
01004

Sponsor information

Organisation
Kiev City Heart Centre (Ukraine)

Sponsor details
Bratislava, 5a
Kiev
Ukraine
02 660

Sponsor type
Hospital/treatment centre

Website
http://www.heart.kiev.ua/en

Funder(s)

Funder type
Other

Funder Name
Cardiovascular surgeons Association (Ukraine)

Funder Name
Kiev city therapeutic society (Ukraine)

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