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Observational study on the hypertensive patients treated with Perindopril-Amlodipine

Submission date
24/07/2013

Recruitment status
No longer recruiting

Registration date
05/08/2013

Overall study status
Completed

Last Edited
31/03/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Cardiovascular diseases are a leading cause of death worldwide and high blood pressure remains the leading risk factor for early death and is responsible for 7.5 million deaths worldwide, according to a report from the World Health Organization. Recent reports suggest that nearly one billion people had high blood pressure in 2000 and this will increase to around 1.56 billion by 2025. Treating high blood pressure reduces the risk of heart disease by 16% and stroke by 36%. Although lifestyle modifications, such as quitting smoking, losing weight and changes in diet can help reduce blood pressure (BP), many patients also need drug therapy. This study aims to find out the effectiveness and safety of different recommended doses of a Perindopril/Amlodipine fixed dose combination treatment (COVERAM).

Who can participate?
Patients already treated for moderate to severe high blood pressure who have not developed any heart disease can participate in this study.

What does the study involve?
There are no medical procedures involved in this study. Patients must be already on COVERAM prior to the study enrollment and the treatment of patients should be done according to the normal clinical practices. Patients who are not on COVERAM will receive a diuretic drug (increases production of urine) as an add on.

What are the possible benefits and risks of participating?
Participants will have the chance of achieving blood pressure control according to their background therapy, further diseases and number of risk factors for heart disease. Common side effects (occur in less than one in ten users) include headache, dizziness, pins and needles, sleepiness, vision disturbances, sensation of noise in the ears, very fast heartbeat, flushing (hot or warm feeling in your face), light-headedness due to low blood pressure, cough, shortness of breath, nausea (feeling sick), vomiting (being sick), abdominal pain, taste disturbances, difficulty in digesting food, watery stool, constipation, allergic reactions (such as skin rashes, itching), muscle cramps, feeling of tiredness, swelling of legs or ankles.

Where is the study run from?
The study will be running in 70 sites (private clinics) across Egypt.

When is the study starting and how long is it expected to run for?
The study starts in August 2013. Patients will be recruited for 3 months. The duration of the treatment is 3 months.

Who is funding the study?
The study is sponsored by Servier Egypt Scientific Office, Egypt.

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
IC4-05985-001-EGY

Study information

Scientific Title
Open labeled Non-Interventional Study to assess EffiCacy & tolerability evaluation of PerindOpril-AmlodipiNe fixed dose combinaTion with oR without addition of Diuretics for uncOntrolled hypertensive patients in the cLinical setting, CONTROL Study

Acronym
CONTROL

Study objectives
"CONTROL study" is an observational study to assess efficacy & Safety evaluation of Perindopril-Amlodipine
fixed dose combination with or without addition of Diuretics for uncontrolled hypertensive patients in the clinical setting.

Coveram - summary of product characteristics
http://www.servier.com/sites/default/files/FR-H-325-01-04-Compiled%20PI-EU-20100429.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved on 04/06/2013 from the Ethics committee of the Egyptian Ministry of Health and Population-Central Directorate for Research and Health Development. Approval number: 18-2013/4

Study design
Multicenter prospective non-interventional study with 3 months follow up

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Screening

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
Cardiovascular area-Hypertension

Interventions
CONTROL study is a multicenter, prospective, Non-Interventional, study among hypertensive patients with
3 months follow up. The study will be approved by local institutional review boards and all patients will give
informed consent in accordance with national and local guidelines.

Duration of study participation:
Study enrollment period is expected to be Three months starting from 1/7/2013.
Each subject should receive at least one dose of COVERAM prior to the study enrollment period.
Screening period should be after first dose of COVERAM and prior to follow-up period.
The study will be considered completed for a patient at the time he/she completes three months of the study duration.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
COVERAM (Perindopril-Amlodipine)

Primary outcome measure
According to the guidelines and the normal clinical practice: at the doctors office after 5 min of rest, sitting position. Three BP measurements have to be taken and the mean of the last two will be used for the calculation of mean.
Assessment of Study Medicines:
Efficacy: Reduction in blood pressure to target values (140/90 mmHg or 130/80 mmHg, in patients with
diabetes mellitus).
Safety: Occurrence of any side effect leading to treatment discontinuation.
All side effects will be monitored at each visit following the baseline visit during the study period.

Secondary outcome measures
1. Percentage of patients achieving blood pressure control according to their background therapy, co-morbidity & number of cardiovascular risk factors.
2. Percentage of patients achieving blood pressure control with the different doses of Perindopril/Amlodipine combination or after adding Indapamide 1.5 mg SR or other treatment modification.
3. Effect of perindopril/Amlodipine combination with or without Indapamide SR or other treatment
modification on short-term intravisit BPV and long-term visit-to-visit variability in SBP & DBP, its relationship
with patient risk factors & comorbidities
4. Occurrence of any side effects leading to treatment discontinuation.

Overall study start date
01/08/2013

Completion date
15/01/2014

Eligibility

Key inclusion criteria

Subjects meeting all of the following criteria will be considered for enrollment into the study:
1. Men or women with age between 30 and 75.
2. Patients with proved hypertension, a baseline mean BP > 140/90 mm Hg with or without Diabetes Mellitus type II.
3. Patients should be taking Coveram prior to enrollment in the study.
4. All patients will be treated for their hypertension with COVERAM as per the decision of the treating physician and according to the Product information leaflet PIL. The decision for treatment with COVERAM will be made by the treating physician, based on medical judgment, prior to assessment of eligibility for the study. The management of the patient by the treating physician including the initiation of treatment with COVERAM will be independent and not affected by participation in the study.
5. Medical history of the patients should include switching of uncontrolled hypertensive patients on at least two medications to Coveram prior to the enrollment of the patients in the study.
6. Medical history of the patients should include switching to COVERAM from previous antihypertensive medication including at least 2 medications amongst ACEIs, ARBs, Diuretics & CCBs.
7. The patient must read, sign and receive a copy of the informed consent prior to study enrollment.
8. Patients registered to this study must be treated and followed up at the participating center according to the normal clinical practice.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
700

Total final enrolment
411

Key exclusion criteria
Subjects presenting with any of the following criteria will not be included in the study:
1. Newly diagnosed hypertensive patients not receiving any treatment at baseline or uncontrolled hypertensive patients receiving only one medication.
2. Hypertensive patients already treated with beta blockers at baseline or those with medical conditions that require to be treated with BB according to guidelines.
3. Patients with secondary hypertension.
4. Patients with stable coronary artery disease including those with MI history or stable angina pectoris.
5. Myocardial infarction, percutaneous coronary intervention, coronary artery bypass graft, or unstable angina pectoris within the past 6 months.
6. Hypertensive encephalopathy, stroke, or transient ischemic attack within the past 12 months.
7. New York Heart Association functional class I-IV congestive heart failure.
8. Hemodynamically significant cardiac valvular disease, Cardiac arrhythmias, sinus tachycardia.
9. Significant chronic renal impairment defined by estimated Glomerular Filtration Rate as those

having eGFR ≤ 60 ml/min/1.73 m2.
10. Significant liver disease as shown by SGPT/SGOT 2.5 times the upper limit of the normal range.
11. Gastrointestinal disease or surgery that might interfere with drug absorption.
12. Malignancy during the past 5 years.
13. Currently pregnant or lactating females.
14. Women of childbearing potential not protected by effective contraceptive method of birth control and/or
who are unwilling or unable to be tested for pregnancy.
15. Known hypersensitivity to Perindopril, other ACEIs, Amlodipine, other CCB, Indapamide, other thiazide diuretic or other antihypertensive treatment use during the follow-up.
16. Simultaneous or previous participation in the 90 days prior to study entry in a clinical trial using an
experimental drug or device.
17. Medical, psychiatric, or neurologic condition that renders the patient unable to understand the nature, scope, and possible consequences of the study or mental retardation or language barrier such that the patient is unable to give informed consent.
18. Any medical condition that in judgment of the investigator would jeopardize the patients safety or the study drugs evaluation for efficacy and safety.
19. Any of the contraindications linked to Perindopril, Amlodipine or COVERAM

Date of first enrolment
01/08/2013

Date of final enrolment
15/01/2014

Locations

Countries of recruitment
Egypt

Study participating centre
Director of cardiac cath. Lab
Alexandria
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21599

Sponsor information

Organisation
Servier Egypt Scientific Office (Egypt)

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Sponsor type
Industry

Website
http://www.servier.com/

ROR
https://ror.org/00v3zdx13

Funder(s)

Funder type
Industry

Funder Name
Servier Egypt Scientific Office (Egypt)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	conference abstract	01/06/2015	31/03/2020	No	No