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Evaluation of heart rate lowering effects with ivabradine in patients with angina in the hospital

Submission date
29/12/2022

Recruitment status
No longer recruiting

Registration date
07/02/2023

Overall study status
Completed

Last Edited
07/02/2023

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
Angina pectoris is chest pain or discomfort due to coronary heart disease. Several studies have proven the benefit of Ivabradine, not only in the management of angina pectoris. The aim of this study is to observe, under actual prescribing conditions over a period of 4 months, the effects of an exclusive reduction of heart rate with Ivabradine in angina coronary patients.

Who can participate?
Patients aged 18 years and older with stable coronary artery disease

What does the study involve?
All patients for whom the investigator prescribed ivabradine in accordance with current clinical practice for treating patients with angina. Their heart rate is measured and their functional improvement graded using the Canadian Cardiovascular Society grading of Angina Pectoris system. Physician satisfaction is also graded to determine the tolerance, efficacy and effectiveness of ivabradine.

What are the possible benefits and risks of participating?
There are no risks to the participants.

Where is the study run from?
Sponsored by Servier Morocco, managed by Gaya CRO (Morocco)

When is the study starting and how long is it expected to run for?
October 2017 to April 2019

Who is funding the study?
Servier Maroc (Morocco)

Who is the main contact?
Fouzia EL HARRANE, fouzia.el-harrane@servier.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
IC4-16257-007-MAR

Study information

Scientific Title
ESSENTIEL Hospital: observation of exclusive heart rate reduction effects with ivabradine in angina patients in a hospital setting

Acronym
ESSENTEIL

Study objectives
This is an observational study to observe the effects of an exclusive reduction of heart rate (HR) with ivabradine in stable coronary artery disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/03/2018, Ethics Committee for Biomedical Research (CERB; Faculty of Medicine and Pharmacy- Rabat, Imp. Souissi, Rabat 10100, Morocco; +212 (0)537773560; guedirak@yahoo.fr), ref: 61/18

Study design
Non-interventional non-comparative open cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary artery disease (CAD) and angina

Interventions
This is an observational study. Each investigator recruited 10 patients presenting symptomatic stable coronary artery disease. The decision to prescribe ivabradine was made by the physician independently of the patient's inclusion in the study.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ivabradine (Coralan)

Primary outcome(s)
1. HR measured by electrocardiogram at baseline, after 1 month and after 4 months
2. CCS grades determined using the Canadian Cardiovascular Society grading of angina pectoris system at baseline, after 1 month and after 4 months

Key secondary outcome(s))
Physician satisfaction assessed by rating the tolerability, efficacy, and effectiveness of ivabradine on a scale of 0 to 5 after 4 months of ivabradine treatment

Completion date
02/04/2019

Eligibility

Key inclusion criteria
Inclusion criteria: as per current SmPC
1. Patients 18 years and older
2. Female or male
3. Patients with documented stable coronary artery disease with or without left ventricular dysfunction (LVD); example: with angina, history of revascularization, history of myocardial infarction, or angiographic evidence of at least 70% stenosis of one of the major coronary arteries
4. Patient with stable angina diagnosed more than 6 months ago
5. HR resting >70 bpm
6. Patients inadequately controlled despite an optimal dose of beta-blockers

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Total final enrolment
125

Key exclusion criteria
Exclusion criteria: according to current SmPC
1. Known hypersensitivity to the active substance or any of the excipients
2. Resting heart rate of fewer than 70 beats per minute prior to treatment
3. Cardiogenic shock
4. Acute myocardial infarction
5. Severe hypotension (<90/50 mmHg)
6. Severe liver failure
7. Sick sinus syndrome
8. Atrial sinus block
9. Unstable or acute heart failure
10. Pacemaker-dependent patient (heart rate exclusively imposed by the pacemaker)
11. Unstable angina
12. Third-degree atrioventricular (AV) block
13. Combination with potent cytochrome P450 3A4 inhibitors, such as azole antifungals (ketoconazole, itraconazole), macrolide antibiotics (clarithromycin, erythromycin per os, josamycin, telithromycin), protease inhibitors (nelfinavir, ritonavir) or nefazodone
14. Combination with verapamil or diltiazem, moderate CYP 3A4 inhibitors with bradycardic effects
15. Pregnancy, breastfeeding and women of childbearing age not using effective contraception

Date of first enrolment
05/01/2018

Date of final enrolment
02/04/2019

Locations

Countries of recruitment
Morocco

Study participating centre
Cardiologists (Public and Private Sector)
Casablanca, Rabat, Marrakech, Fes, Agadir, Benimellal, Oujda
Morocco
10000

Sponsor information

Organisation
Servier Maroc

Funder(s)

Funder type
Industry

Funder Name
Servier Maroc

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed in the current study are not expected to be made available due to the data privacy of Morocco.

IPD sharing plan summary
Not expected to be made available