

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/02/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/02/2023	Condition category 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

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**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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

Overall study start date

30/10/2017

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

125

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

Sponsor details

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Sponsor type

Industry

Website

<https://servier.ma/>

Funder(s)

Funder type

Industry

Funder Name

Servier Maroc

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal in 2023

Intention to publish date

31/12/2023

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