

Long-term (3 years) ophthalmic safety and cardiac efficacy and safety of ivabradine administered orally at the therapeutic doses (2.5 /5/7.5 mg twice daily [b.i.d.]) on top of anti-anginal background therapy, to patients with chronic stable angina pectoris

Submission date 18/01/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/02/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/04/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-005475-17

Protocol serial number

Study information

Scientific Title

Long-term (3 years) ophthalmic safety and cardiac efficacy and safety of ivabradine administered orally at the therapeutic doses (2.5/5/7.5 mg b.i.d.) on top of anti-anginal background therapy, to patients with chronic stable angina pectoris. An international, double-blind placebo controlled study.

Study objectives

The inhibition of the Hyperpolarization-activated (I_h) current present in the retina by ivabradine administered at the recommended doses leads to transient functional modifications of the retina.

As of 23/07/2012, the following changes were made to this record:

1. The anticipated end date was extended from 01/05/2014 to 30/09/2015
2. The target number of participants was reduced from 300 to 100

As of 03/03/2011 the anticipated end date for this trial has been updated from 01/11/2012 to 01/05/2014.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the First Portuguese Ethics Committee on the 15/01/2008

Study design

International, parallel, double-blind placebo-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic stable angina pectoris

Interventions

1. 2.5 mg ivabradine orally (po)
2. 5 mg ivabradine po
3. 7.5 mg ivabradine po
4. Matching placebo

Patients will receive treatment for 3 years.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ivabradine

Primary outcome(s)

To document the absence of retinal toxicity in chronic stable angina patients assessed by ocular tests performed 2 months after a treatment exposure of 3 years.

Key secondary outcome(s)

To document the long term cardiac efficacy and general ocular, cardiac and general safety.

Completion date

30/09/2015

Eligibility**Key inclusion criteria**

1. Male or female patients (oral contraception if childbearing potential), aged greater than 18 years or having reached majority if the legal age of majority is above 18 years age and of any ethnic origin
2. Patients in sinus rhythm; resting heart rate greater than 60 beats per minute, with a history of chronic stable angina greater than 3 months before selection, no angina at rest and with a clinically stable angina greater than 3 months, at least 1 angina attack per month during the previous 3 months before selection
3. Patients who accept to undergo repeated visual tests and with a visual acuity greater than 0.5

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

97

Key exclusion criteria

1. Contra-indication to the administration of ivabradine
2. Patients with marked ocular conditions (significant altered vision and/or any evolutive underlying disease) known to have an impact on the ocular tests planned in the protocol

Date of first enrolment

01/03/2008

Date of final enrolment

30/09/2015

Locations

Countries of recruitment

Argentina

Australia

Belgium

Finland

Germany

Hungary

Ireland

Portugal

Singapore

Sweden

Study participating centre

Med. Univ. Klinik und Poliklinik - Abt. Für Kardiologie

Hamburg

Germany

20246

Sponsor information

Organisation

Institut de Recherches Internationales Servier (France)

ROR

<https://ror.org/034e7c066>

Funder(s)

Funder type

Industry

Funder Name

Institut de Recherches Internationales Servier (France)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from <https://clinicaltrials.servier.com> if a Marketing Authorisation has been granted after 1st January 2014.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Basic results			21/04/2020	No	No