ISRCTN99185656 https://doi.org/10.1186/ISRCTN99185656

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/02/2008	**Overall study status** Completed	
Last Edited 21/04/2020	**Condition category** Circulatory System	

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
Prof Thomas Meinertz

Contact details
Med. Univ. Klinic und Poliklinic - Abt. Für Kardiologie
Martinistr. 52
Hamburg
Germany
20246

Additional identifiers

Clinical Trials Information System (CTIS)
2006-005475-17

Protocol serial number

CL3-16257-067

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 (Ih) 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

Primary study design
Interventional

Study design
International, parallel, double-blind placebo-controlled study

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. Klinic und Poliklinic - 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