

Effects of ivabradine on cardiovascular events in patients with moderate to severe chronic heart failure and left ventricular systolic dysfunction

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| Submission date 25/07/2006 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 14/08/2006 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 26/06/2020 | 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

EudraCT/CTIS number

2006-000708-18

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CL3-16257-063

Study information

Scientific Title

Effects of ivabradine on cardiovascular events in patients with moderate to severe chronic heart failure and left ventricular systolic dysfunction: a three-year randomised double-blind placebo-controlled international multicentre study

Acronym

SHIFT

Study objectives

Demonstrate the superiority of ivabradine over placebo in the reduction of cardiovascular mortality and hospitalisations for worsening heart failure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First French Ethics Committee approval obtained on 06/06/2006 from the CCPPRB Ambroise Paré (dossier: 06 06 46).

Study design

Double-blind randomised placebo-controlled two parallel and balanced treatment arms study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Chronic heart failure

Interventions

S16257 tablets containing 2.5 or 5 or 7.5 mg of ivabradine versus matching placebos.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ivabradine

Primary outcome measure

Composite endpoint made of cardiovascular mortality or hospitalisation for worsening heart failure

Secondary outcome measures

Composite and non-composite endpoints including all deaths and all hospitalisations, change in functional capacity and clinical symptoms of heart failure

Overall study start date

15/09/2006

Completion date

30/04/2010

Eligibility**Key inclusion criteria**

1. Male or female aged more than 18 years
2. Chronic heart failure
3. Left ventricular systolic dysfunction
4. Sinus rhythm

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

6500

Key exclusion criteria

1. Unstable cardiovascular condition
2. Recent myocardial infarction or coronary revascularisation

3. Congenital heart disease
4. Severe valvular disease
5. Active myocarditis

Date of first enrolment

15/09/2006

Date of final enrolment

30/04/2010

Locations

Countries of recruitment

Argentina

Australia

Austria

Belgium

Brazil

Bulgaria

Canada

Chile

China

Czech Republic

Denmark

Estonia

Finland

France

Germany

Greece

Hong Kong

Hungary

India

Ireland

Italy

Korea, South

Latvia

Lithuania

Malaysia

Netherlands

Norway

Poland

Portugal

Romania

Russian Federation

Slovakia

Slovenia

Spain

Sweden

Türkiye

Ukraine

United Kingdom

Study participating centre

Göteborg University

Göteborg

Sweden

S 416 85

Sponsor information

Organisation

Institut de Recherches Internationales Servier (France)

Sponsor details

50 rue Carnot
Suresnes
France
92284

Sponsor type

Industry

Website

<http://www.servier.com/>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan

Publication plan:

Summary results are published on <https://clinicaltrials.servier.com>.

For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

Intention to publish date

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? |
|-------------|---------|--------------|------------|----------------|-----------------|
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|----------------------------------|----------|------------|------------|-----|----|
| Basic results | | | | No | No |
| Protocol article | protocol | 01/01/2010 | | Yes | No |
| Results article | results | 11/09/2010 | | Yes | No |
| Results article | results | 11/09/2010 | | Yes | No |
| Results article | results | 29/05/2012 | | Yes | No |
| Results article | results | 19/11/2013 | | Yes | No |
| Results article | results | 12/02/2016 | | Yes | No |
| Results article | results | 24/03/2017 | | Yes | No |
| Results article | results | 01/07/2020 | 26/06/2020 | Yes | No |