

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

Submission date 25/07/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 14/08/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/06/2020	Condition category Circulatory System	☐ 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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Additional identifiers

Clinical Trials Information System (CTIS)

2006-000708-18

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

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

Study participating centre

Göteborg University

Göteborg

Sweden

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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?
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
Protocol article	protocol	01/01/2010		Yes	No
Basic results				No	No