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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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/08/2006	**Overall study status** Completed	
Last Edited 26/06/2020	**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

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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
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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?

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