







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

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|--|---|--|
| <b>Submission date</b><br>25/07/2006   | <b>Recruitment status</b><br>No longer recruiting |  Prospectively registered |
|  |   |  Protocol added           |
| <b>Registration date</b><br>14/08/2006 | <b>Overall study status</b><br>Completed          |  SAP not yet added        |
|  |   |  Results added            |
| <b>Last Edited</b><br>26/06/2020       | <b>Condition category</b><br>Circulatory System   |  Raw data not yet added   |
|  |   |  Study completed          |

## Plain English Summary

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

## Contact information

### Type(s)

Scientific

### Contact name

Prof Karl Swedberg

### Contact details

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S 416 85

## Additional identifiers

### EudraCT/CTIS number

2006-000708-18

### IRAS number

**ClinicalTrials.gov number**

**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 hypothesis**

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

### **Condition**

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

**Overall study end date**

30/04/2010

**Eligibility****Participant 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

**Participant exclusion criteria**

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

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

**Recruitment start date**

15/09/2006

**Recruitment end date**

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

Turkey

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? |
|-------------|---------|--------------|------------|----------------|-----------------|
|-------------|---------|--------------|------------|----------------|-----------------|

|                                  |          |            |            |     |    |
|----------------------------------|----------|------------|------------|-----|----|
| <a href="#">Basic results</a>    |          |            |            | No  | No |
| <a href="#">Protocol article</a> | protocol | 01/01/2010 |            | Yes | No |
| <a href="#">Results article</a>  | results  | 11/09/2010 |            | Yes | No |
| <a href="#">Results article</a>  | results  | 11/09/2010 |            | Yes | No |
| <a href="#">Results article</a>  | results  | 29/05/2012 |            | Yes | No |
| <a href="#">Results article</a>  | results  | 19/11/2013 |            | Yes | No |
| <a href="#">Results article</a>  | results  | 12/02/2016 |            | Yes | No |
| <a href="#">Results article</a>  | results  | 24/03/2017 |            | Yes | No |
| <a href="#">Results article</a>  | results  | 01/07/2020 | 26/06/2020 | Yes | No |