

# Effects of ivabradine in patients with stable coronary artery disease without heart failure

<b>Submission date</b> 28/08/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/09/2019	<b>Condition category</b> 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

Prof Kim Fox

### Contact details

Sydney Street  
London  
United Kingdom  
SW3 6NP

## Additional identifiers

### Clinical Trials Information System (CTIS)

2009-011360-10

### ClinicalTrials.gov (NCT)

NCT02446990

### Protocol serial number

CL3-16257-083

## Study information

Scientific Title

Effects of ivabradine in patients with stable coronary artery disease without clinical heart failure: a randomised double-blind placebo-controlled international multicentre study

**Acronym**

SIGNIFY

**Study objectives**

To evaluate the effect of ivabradine on cardiovascular events in patients with coronary artery disease.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval was obtained before recruitment of the first participants

**Study design**

Randomised double-blind placebo-controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Coronary artery disease

**Interventions**

Ivabradine/placebo tablets for up to 48 months.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

The effect of ivabradine on cardiovascular events, measured up to 48 months.

**Key secondary outcome(s)**

Measured up to 48 months:

1. Efficacy
2. Safety

**Completion date**

03/09/2013

**Eligibility**

**Key inclusion criteria**

1. Aged 55 years or older
2. Male or female
3. Patients with stable coronary artery disease without clinical heart failure
4. Sinus rhythm and resting heart rate equal or higher than 70 bpm

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Unstable cardiovascular condition
2. Contra-indication to ivabradine

**Date of first enrolment**

01/09/2009

**Date of final enrolment**

03/09/2013

**Locations****Countries of recruitment**

United Kingdom

England

Argentina

Armenia

Australia

Austria

Belarus

Belgium

Brazil

Bulgaria

Canada  
China  
Croatia  
Czech Republic  
Denmark  
Estonia  
Finland  
France  
Georgia  
Germany  
Greece  
Hong Kong  
Hungary  
India  
Ireland  
Italy  
Kazakhstan  
Korea, South  
Latvia  
Lithuania  
Malaysia  
Mexico  
Netherlands  
North Macedonia  
Norway  
Philippines

Poland

Portugal

Romania

Russian Federation

Serbia

Singapore

Slovakia

Slovenia

South Africa

Spain

Sweden

Switzerland

Taiwan

Thailand

Türkiye

Ukraine

Uruguay

Viet Nam

**Study participating centre**

**Sydney Street**

London

United Kingdom

SW3 6NP

## **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 2014.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2013		Yes	No
<a href="#">Results article</a>	results	18/09/2014		Yes	No
<a href="#">Results article</a>	results	07/12/2015		Yes	No
<a href="#">Basic results</a>				No	No
<a href="#">Basic results</a>			10/09/2019	No	No