

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

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

2009-011360-10

IRAS number

ClinicalTrials.gov number

NCT02446990

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Coronary artery disease

Interventions

Ivabradine/placebo tablets for up to 48 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

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

Secondary outcome measures

Measured up to 48 months:

1. Efficacy
2. Safety

Overall study start date

01/09/2009

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

Age group

Adult

Sex

Both

Target number of participants

16850

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

Argentina

Armenia

Australia

Austria

Belarus

Belgium

Brazil

Bulgaria

Canada

China

Croatia

Czech Republic

Denmark

England

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

United Kingdom

Uruguay

Viet Nam

Study participating centre

Sydney Street
London
United Kingdom
SW3 6NP

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:

All phases - Interventional studies ending before 01/10/2018: Summary results will be published on <https://clinicaltrials.servier.com/> within 12 months after the end of the study.

All phases - Interventional studies ending after 01/10/2018: Summary results and a lay summary will be published on <https://clinicaltrials.servier.com/> within 12 months after the end of the study.

Phase 3 only - The results will be published in scientific literature within 18 months after the end of the study.

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 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
Results article	results	01/10/2013		Yes	No
Results article	results	18/09/2014		Yes	No
Results article	results	07/12/2015		Yes	No
Basic results			10/09/2019	No	No