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

Submission date 28/08/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/09/2009	**Overall study status** Completed	
Last Edited 10/09/2019	**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

Contact name
Prof Kim Fox

Contact details
Sydney Street
London
United Kingdom
SW3 6NP

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