ISRCTN66067800 https://doi.org/10.1186/ISRCTN66067800

Evaluation versus placebo of the effects on heart rate, haemodynamic parameters, safety and tolerability of 5 mg bolus of ivabradine followed by 8-hour infusion of 5 mg of ivabradine, given to patients undergoing a percutaneous coronary intervention following a myocardial infarction with ST segment elevation (STEMI): a pilot, blind, randomised, placebo-controlled, international, multi-centre study including the ancillary sub-study to the clinical study protocol

Submission date
06/08/2008

Registration date
25/09/2008

Last Edited
18/04/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
2005-005122-31

Protocol serial number
CL2-16257-060

Study information

Scientific Title
Evaluation versus placebo of the effects on heart rate, haemodynamic parameters, safety and tolerability of 5 mg bolus of ivabradine followed by 8-hour infusion of 5 mg of ivabradine, given to patients undergoing a percutaneous coronary intervention following a myocardial infarction with ST segment elevation (STEMI): a pilot, blind, randomised, placebo-controlled, international, multi-centre study including the ancillary sub-study to the clinical study protocol

Acronym
VIVIFY

Study objectives
Evaluate the effect of ivabradine over placebo on heart rate and haemodynamic parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The First French Ethics Committee gave approval on the 11/01/2006 from CCPPRB paris-Pitié-Salpêtrière (dossier 103-05)

Study design
Randomised, blinded, placebo-controlled, two parallel and unbalanced treatment arms study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute myocardial infarction with ST segment elevation (STEMI) leading to a percutaneous coronary intervention

Interventions

Intravenous injection of 5 mg/placebo, followed by 5 mg/placebo infusion during 8 hours of ivabradine.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ivabradine

Primary outcome(s)
Effect on heart rate and blood pressure from the time of drug administration to 24 hours.

Key secondary outcome(s))
1. Cardiac markers (successive measurements during the 24 hours post-drug administration)
2. Echocardiography parameters (6 to 48 hours post-drug administration)
3. Magnetic resonance imaging parameters (sub-study) prior to discharge and at month 4
4. Pharmacokinetics measurements (during 24 hours post-study drug administration)

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. Male or female of non-childbearing potential, aged 40 to 80 years
2. Patients who are undergoing a percutaneous coronary intervention following an acute myocardial infarction with ST segment elevation
3. Sinus rhythm
4. Heart rate greater than 80 beats per minute
5. Systolic blood pressure greater than 90 mmHg

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Sick sinus syndrome, second-degree or third degree atrioventricular (AV) block
2. Atrial fibrillation or flutter

3. Hypertrophic cardiomyopathy, severe valvular disease or congenital disease
4. Moderate or severe liver disease
5. Unstable vital signs at clinical examination, stage IV Killip heart failure
6. Moderate or severe renal failure as measured by glomerular filtration rate (GFR) less than 60 ml/min/1.73m^2 of body surface area

Date of first enrolment
19/05/2006

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
Australia

Belgium

France

Germany

Spain

Study participating centre
Centre Hospitalier Bichat-Claude Bernard
Paris
France
FR-75877

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 1st January 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2013		Yes	No
Basic results				No	No