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	Recruitment status No longer recruiting	Prospectively registered		
06/08/2008		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/09/2008	Completed	[X] Results		
Last Edited 18/04/2018	Condition category Circulatory System	[] 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 Philippe Steg

Contact details

Centre Hospitalier Bichat-Claude Bernard Cardiology Department 46 rue Henri Huchard Paris France 75877

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 mmHq

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

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 ad	ded Peer review	ed? Patient-facing?
Results article	results	01/09/2013	Yes	No
Basic results			No	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2	025 No	Yes