

Effects of a 10 or 15 mg single intravenous bolus of ivabradine versus placebo on heart rate control during a multislice computed tomography coronary angiography for the evaluation of coronary artery disease

Submission date 07/11/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/12/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/03/2018	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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Additional identifiers

Clinical Trials Information System (CTIS)

2007-006793-28

Protocol serial number

CL3-16257-078

Study information

Scientific Title

Effects of a 10 or 15 mg single intravenous bolus of ivabradine versus placebo on heart rate control during a multislice computed tomography coronary angiography for the evaluation of coronary artery disease: a randomised, double-blind, international, multi-centre study

Study objectives

Evaluate the effect of a 10 or 15 mg single intravenous bolus of ivabradine versus placebo on heart rate control during a multislice computed tomography coronary angiography (MSCT-CA) for the evaluation of coronary artery disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee for Protection of Human Subjects (CPP) Ile de France IX Créteil, France, 03/07/2008

Study design

Randomised double-blind placebo-controlled trial

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Multislice computed tomography coronary angiography for the evaluation of coronary artery disease

Interventions

10 or 15 mg single intravenous bolus administration of ivabradine/placebo.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Ivabradine

Primary outcome(s)

Heart rate control ≤ 65 bpm at the time of initiation of image acquisition during MST CA procedure.

Key secondary outcome(s)

1. Safety of intravenous ivabradine during and after MSCT CA procedure until 3 days after ivabradine administration
2. Pharmacokinetics

Completion date

31/05/2010

Eligibility

Key inclusion criteria

1. Male or female patients of non-childbearing potential ≥ 18 years
2. Planned to undergo a scheduled multislice computed tomography coronary angiography
3. Not eligible for intravenous beta-blockers
4. Electrocardiographic documentation of sinus rhythm and a stable heart rate ≥ 70 bpm

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Current unstable clinical condition
2. New York Heart Association (NYHA) functional classification IV
3. Scheduled coronary revascularisation
4. Permanent atrial fibrillation or flutter
5. Severe obstructive valvular disease, congenital heart disease
6. Implanted pacemaker with atrial or ventricular permanent pacing
7. Sick sinus syndrome or sinoatrial block
8. Second or third degree atrio-ventricular block

Date of first enrolment

01/10/2008

Date of final enrolment

31/05/2010

Locations

Countries of recruitment

United Kingdom

Australia

Belgium

Brazil

Bulgaria

Denmark

France

Germany

Hungary

Italy

Korea, South

Netherlands

Poland

Portugal

Romania

Russian Federation

Singapore

South Africa

Spain

Taiwan

Study participating centre

Albinusdreef 2

Leiden

Netherlands

2333 ZA

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	01/07/2015		Yes	No
Basic results				No	No