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# 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

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| **Submission date**<br>07/11/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>11/12/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>28/03/2018 | **Condition category**<br>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

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## Additional identifiers

**EudraCT/CTIS number**
2007-006793-28

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Diagnostic

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure
Heart rate control <=65 bpm at the time of initiation of image acquisition during MST CA procedure.

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

### Overall study start date
01/10/2008

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
330

### 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
Australia

Belgium

Brazil

Bulgaria

Denmark

France

Germany

Hungary

Italy

Korea, South

Netherlands

Poland

Portugal

Romania

Russian Federation

Singapore

South Africa

Spain

Taiwan

United Kingdom

**Study participating centre**
**Albinusdreef 2**
Leiden
Netherlands
2333 ZA

# 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:
Summary results are published on https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

## 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 1st January 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 | 01/07/2015 | | Yes | No |