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Effects of ivabradine in patients with coronary artery disease and suffering from a reversible contractility dysfunction of the heart muscle

Submission date 09/06/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/10/2011	**Overall study status** Completed	
Last Edited 20/04/2020	**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

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Additional identifiers

Clinical Trials Information System (CTIS)
2011-000783-98

Protocol serial number
CL2-16257-095

Study information

Scientific Title
Effects of oral administration of ivabradine (7.5 mg bid) on post-ischaemic stunning induced by exercise stress in patients with coronary artery disease and exercise inducible ischaemia

Study objectives
To assess the effects of ivabradine on post-ischaemic stunning induced by exercise stress in patients with stable coronary artery disease and exercise-inducible ischaemia

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Exploratory open label study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions
1. Two film-coated tablets of 7.5 mg or 5 mg of ivabradine
2. Control: placebo bid

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
1. Myocardial stunning, by evaluating changes in regional wall motion measuring 2D Strain /Strain rate
2. Measured at selection visit, inclusion visit and end of treatment visit

Key secondary outcome(s))
1. Arterial elastance, measured at selection visit, inclusion visit and end of treatment visit
2. Ventricular arterial coupling, measured at selection visit, inclusion visit and end of treatment visit
3. Safety, measured at each visit

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. Aged 30 to 75 years
2. Male or female
3. Evidence of coronary artery disease proven by clinical history
4. Sinus rhythm and resting heart rate equal or higher than 70 bpm
5. Exercise-inducible myocardial ischaemia
6. Myocardial stunning, assessed by cardiac echocardiography

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
15

Key exclusion criteria
1. Angina at rest or angina class IV
2. Unstable cardiovascular condition
3. Previous treament with anti-anginal medication within 1 week before inclusion
4. Significant abnormalities in the laboratory blood evaluation
5. Contra-indication to the administration of ivabradine

Date of first enrolment
01/09/2011

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
Italy

Study participating centre

San Raffaele University
Milan
Italy
20132

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?
Basic results				No	No
Basic results			20/04/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes