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Clinical acceptability of trimetazidine 80 mg once daily compared to trimetazidine 35 mg twice daily in patients with chronic stable angina pectoris

Submission date
05/03/2012

Recruitment status
No longer recruiting

Registration date
04/04/2012

Overall study status
Completed

Last Edited
21/05/2018

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

Protocol serial number
CL3-06795-008

Study information

Scientific Title

Clinical acceptability of trimetazidine 80 mg once daily compared to trimetazidine 35 mg twice daily in patients with chronic stable angina pectoris: a multicentre randomised double blind study

Study objectives
To compare the clinical acceptability of trimetazidine 80mg once daily with trimetazidine 35 mg twice daily

Ethics approval required
Old ethics approval format

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

Primary study design
Interventional

Study design
International multicentre randomised double-blind parallel-group study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Angina pectoris attacks

Interventions
A randomised, double-blind, parallel-group study in patients treated for 12 weeks - Two arms: trimetazidine MR 80mg once daily or trimetazidine MR 35mg twice daily

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
1. Emergent adverse events
2. Blood pressure
3. Weight
4. Laboratory examinations: biochemical and haematological parameters
5.12-lead electrocardiogram
6. CCS classification of symptoms of angina pectoris

Key secondary outcome(s)
No secondary outcome measures

Completion date

31/12/2012

Eligibility

Key inclusion criteria
1. Male or female patient
2. More than or equal to 21 years old
3. Any ethnic origin
4. Patients with a prior diagnosis of stable angina pectoris of effort

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. History of acute coronary syndrome within previous 3 months
2. Coronary revascularisation procedure within previous 3 months
3. Canadian Cardiovascular Society (CCS) class 4 angina pectoris

Date of first enrolment
12/03/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Russian Federation

Serbia

Study participating centre
Moscow Regional Cardiology Centre
Moscow
Russian Federation
140180

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 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2018		Yes	No
Basic results				No	No
Poster results	poster presentation	27/08/2016		No	No