

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	☐ Prospectively registered
		☐ Protocol
Registration date 04/04/2012	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 21/05/2018	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

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Contact details

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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

Study design

International multicentre randomised double-blind parallel-group study

Primary study design

Interventional

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