

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/04/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 21/05/2018	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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

12/03/2012

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

Age group

Adult

Sex

Both

Target number of participants

150

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)

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

Current version as of 28/03/2018:

Summary results are published in <https://clinicaltrials.servier.com>.

For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

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.

Previous version as of 24/01/2018:

Publication plan:

All phases - Interventional studies ending before 01/10/2018: Summary results will be published on <https://clinicaltrials.servier.com/> within 12 months after the end of the study.

All phases - Interventional studies ending after 01/10/2018: Summary results and a lay summary will be published on <https://clinicaltrials.servier.com/> within 12 months after the end of the study.

Phase 3 only - The results will be published in scientific literature within 18 months after the end of the study.

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 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
Poster results	poster presentation	27/08/2016		No	No
Results article	results	01/06/2018		Yes	No