ISRCTN84362208 https://doi.org/10.1186/ISRCTN84362208

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

Registration date
04/04/2012

Last Edited
21/05/2018

Recruitment status
No longer recruiting

Overall study status
Completed

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

Contact name
Prof Yuri M Pozdnyakov

Contact details
Moscow Regional Cardiology Centre
Zhukovsky
Frunze Street, 1
Moscow
Russian Federation
140180

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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