

Antianginal efficacy of trimetazidine in daily practice

Submission date 23/03/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/04/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/11/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Angina is caused by narrowing of the arteries that supply the heart. Angina causes pain or discomfort that happens when the heart can't get enough blood and oxygen during physical activity or extreme emotion. Angina is common and affects more than 100 million people in the world. Several types of medicines are used to prevent or reduce angina, but the disease is not always well controlled and some patients remain affected and their daily activity can be limited even with treatment.

Who can participate?

Men and women who had stable angina for at least 3 months and were having symptoms despite treatment for angina.

What does the study involve?

All participants took trimetazidine twice daily as well as their other angina medicine.

What are the possible benefits and risks of participating?

The participants might benefit from better control of their angina symptoms (eg reduced pain). The risks of participating include the possibility of side effects to trimetazidine. To reduce risk from participation, doctors monitored patients closely and were empowered to change medication depending on symptoms and side effects. Patients were only included in the study if the doctor thought they might benefit from trimetazidine treatment. Patients were involved in reporting their health status and walking distance assessment and this might give them a more active role in the treatment and monitoring of their angina, which can lead to a more positive outlook and better quality of life. More frequent testing and visits during this study ensured closer monitoring of the effectiveness and tolerability of trimetazidine.

Where is the study run from?

The study was run from the Department of Preventive and Emergency Cardiology, Sechenov First Moscow State University, Moscow, Russia.

When is the study starting and how long is it expected to run for?

The study started in September 2014 and ended in September 2015.

Who is funding the study?
Servier (Russia)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evidence for the antianginal efficacy of trimetazidine in patients with stable angina in daily practice

Acronym
CHOICE-2

Study objectives
The guidelines recommend a beta-blocker or calcium channel blocker as the first-line medication for angina, supplemented by other agents for additional symptoms. One such agent is trimetazidine (TMZ), which has been shown to reduce the frequency of anginal episodes and improve exercise performance without affecting haemodynamic parameters. However,

extensive real-world evidence for its efficacy in combination with first-line therapies has been lacking.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Inter-University Ethics Committee, 23/10/2014, 09-14 dd Moscow

Study design

Multicentre open-label prospective observational study

Primary study design

Observational

Secondary study design**Study setting(s)**

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Stable angina

Interventions

Trimetazidine 35 mg bid was added to antianginal therapy by investigators according to the medical merit and necessity of therapy.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Trimetazidine

Primary outcome measure

Angina frequency and short-acting nitrate use over the 6 months, assessed using patient's diary at baseline, week 2, and months 2, 4, and 6

Secondary outcome measures

1. Walking distance eliciting angina assessed using patient's diary at baseline, week 2, and months 2, 4, and 6. The distance was recorded by patients in diary as the distance they walked (in

- m) before experiencing angina symptoms, in conditions of daily activity, when they walked at their own pace and on mostly flat surfaces.
2. Patient self-reported well-being on a visual analog scale from 0 (very good) to 100 (very bad) at baseline, week 2, and months 2, 4, and 6.

Overall study start date

01/09/2014

Completion date

01/09/2015

Eligibility

Key inclusion criteria

1. Aged >18 years
2. Provided informed consent
3. ≥3-month history of stable angina documented by ECG-confirmed myocardial ischaemia and /or prior myocardial infarction, revascularisation or >50% coronary stenosis, and treated for CAD in the past month.
4. Inclusion was decided solely by physicians according to the medical merit and necessity of treatment with TMZ 35 mg bid

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

896

Total final enrolment

741

Key exclusion criteria

1. Canadian Cardiovascular Society (CCS) class 4 stable angina
2. Hospitalisation in the past 3 months for acute coronary syndrome (infarction or unstable angina)
3. Uncontrolled hypertension (systolic >180 mmHg or diastolic >100 mmHg) despite ongoing antihypertensive treatment
4. New York Heart Association (NYHA) class III or IV heart failure
5. Pregnancy or breastfeeding
6. CAD surgery scheduled in the next 6 months
7. Severe hepatic or renal failure, or other severe chronic disease requiring continuous treatment

- 8. Known poor treatment compliance
- 9. Intolerance or contraindications to TMZ.

Date of first enrolment

01/03/2015

Date of final enrolment

30/04/2015

Locations

Countries of recruitment

Russian Federation

Study participating centre

Sechenov First Moscow State University

Department of Preventive and Emergency Cardiology

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Sponsor information

Organisation

Servier

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Sponsor type

Industry

ROR

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Funder(s)

Funder type

Industry

Funder Name

Servier

Results and Publications

Publication and dissemination plan

Intention to publish date

01/04/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2017		Yes	No
Results article	results	01/07/2018		Yes	No
Other publications	post hoc analysis of trimetazidine in combination with bisoprolol	01/11/2020	30/11/2020	Yes	No