ISRCTN65209863 https://doi.org/10.1186/ISRCTN65209863

Antianginal efficacy of trimetazidine in daily practice

Submission date	Recruitment status	[_] Prospectively registered
23/03/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/04/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/11/2020	Circulatory System	

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
https://ror.org/034e7c066

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