

# Antianginal efficacy of trimetazidine in daily practice

<b>Submission date</b> 23/03/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/04/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/11/2020	<b>Condition category</b> 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?  
Prof. Maria Glezer  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

Moscow  
Russian Federation  
119991

## Sponsor information

Organisation  
Servier

ROR  
<https://ror.org/034e7c066>

## Funder(s)

Funder type  
Industry

Funder Name  
Servier

## Results and Publications

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?
<a href="#">Results article</a>	results	01/04/2017		Yes	No
<a href="#">Results article</a>	results	01/07/2018		Yes	No
<a href="#">Other publications</a>	post hoc analysis of trimetazidine in combination with bisoprolol	01/11/2020	30/11/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes