

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the Efficacy of Oral Theophylline on Clinical Symptoms of Cardiac Syndrome X at Shahid Rajaei Hospital, Karaj

Protocol summary

Study aim

To evaluate the efficacy of oral theophylline on improving clinical symptoms, reducing the frequency and severity of anginal pain, enhancing physical capacity, and improving the quality of life in patients with cardiac syndrome X at Shahid Rajaei Hospital, Karaj

Design

A randomized, placebo-controlled, double-blind, parallel-group, phase 3, single-center clinical trial on 46 patients; Block randomization with variable block sizes of 4 and 6; Allocation concealment using sequentially numbered, opaque, sealed envelopes; Blinding includes patients, data collector/investigator, and statistical analyzer

Settings and conduct

The study will be conducted at the angiography unit and specialized cardiology clinics of Shahid Rajaei Hospital, Karaj; Eligible patients will be screened and enrolled after signing an informed written consent; The standard Seattle Angina Questionnaire (SAQ) will be completed at baseline; Patients will then be randomly allocated to either group, and after 4 weeks of intervention, the SAQ will be completed again to evaluate changes in clinical symptoms

Participants/Inclusion and exclusion criteria

Inclusion: Definite CSX with angina, positive MPI and normal/mild CAD (<50%); Normal EF and no major valvular disease; Exclusion: CAD >50%; Pregnancy; History of seizures or severe ventricular arrhythmias; Severe asthma or COPD; Concurrent use of beta-blockers, CCB, or ranolazine

Intervention groups

Intervention group: Patients receive oral theophylline tablets 100 mg daily for 4 weeks; Control group: Patients receive placebo tablets, completely identical in appearance, color, taste, and packaging to the active drug, for 4 weeks

Main outcome variables

Changes in the scores of the 5 dimensions of the Seattle Angina Questionnaire (SAQ) including: physical

limitation; angina stability; angina frequency; treatment satisfaction; quality of life; before and after 4 weeks of intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260619069872N1**

Registration date: **2026-06-29, 1405/04/08**

Registration timing: **prospective**

Last update: **2026-06-29, 1405/04/08**

Update count: **0**

Registration date

2026-06-29, 1405/04/08

Registrant information

Name

Mostafa Kalvandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3250 7699

Email address

mostafakal1375@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-06, 1405/04/15

Expected recruitment end date

2026-12-06, 1405/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the Efficacy of Oral Theophylline on Clinical Symptoms of Cardiac Syndrome X at Shahid Rajaei Hospital, Karaj

Public title
Evaluation of the effect of oral theophylline on clinical symptoms of patients with cardiac syndrome X

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Definite diagnosis of Cardiac Syndrome X with anginal chest pain and positive myocardial perfusion imaging scan Normal coronary arteries or mild coronary artery disease less than 50 percent on angiography Normal ejection fraction on echocardiography Absence of significant valvular heart disease
Exclusion criteria:
Coronary artery stenosis greater than 50 percent on angiography Pregnancy or lactation History of seizures or severe ventricular arrhythmias Severe asthma or severe chronic obstructive pulmonary disease Concomitant use of beta-blockers or calcium channel blockers or ranolazine

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomized in a 1 to 1 ratio into the intervention or control groups using block randomization with variable block sizes of 4 and 6 The allocation sequence will be generated by an independent epidemiologist using Stata software To ensure allocation concealment the assignments will be placed in sequential numbered opaque and sealed envelopes Upon enrollment of each participant the corresponding envelope will be opened to determine the treatment assignment

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is designed as a double blind clinical trial Theophylline 100mg tablets and placebos will be manufactured to be completely identical in appearance color packaging and taste Patients the investigator who

collects data and the statistician who analyzes data will remain fully blinded to the group allocations until the statistical analysis is completed

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق در پژوهش دانشگاه علوم پزشکی البرز
Street address
متری گلشهر، کوچه صفاریان، معاونت تحقیقات و فناوری ۴۵
دانشگاه علوم پزشکی البرز
City
کج
Province
Alborz
Postal code
3198764653

Approval date
2026-06-06, 1405/03/16

Ethics committee reference number
IR.ABZUMS.REC.1405.101

Health conditions studied

1

Description of health condition studied
Cardiac Syndrome X (Microvascular Angina)
ICD-10 code
I20.8
ICD-10 code description
Other forms of angina pectoris

Primary outcomes

1

Description
Mean scores of the Seattle Angina Questionnaire dimensions including physical limitation, angina stability, angina frequency, treatment satisfaction, and quality of life

Timepoint
At baseline before the intervention and four weeks after the initiation of the theophylline or placebo intervention

Method of measurement
Completion of the standardized international Seattle Angina Questionnaire and calculating each dimension score on a scale of 0 to 100 according to the official tool protocol

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group receive oral theophylline tablets 100 mg once daily for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: Control group: Patients receive placebo tablets completely identical in appearance, color, taste, and packaging to the active drug once daily for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز آموزشی درمانی شهید رجایی کرج

Full name of responsible person

دکتر علیرضا دهقان نیری

Street address

حصارک، خیابان شهید رجایی، مرکز آموزشی و درمانی شهید رجایی

City

کرج

Province

Alborz

Postal code

3197635141

Phone

+98 26 3464 3774

Email

ama_dehghan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Alireza Dehghan Nayeri

Street address

Vice Chancellor for Research and Technology,
Saffarian Alley, 45-Meter Golshahr Blvd

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3705

Email

Research@abzums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Karaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mostafa Kalvandi

Position

Cardiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

Unit 3, Sayeh Building, No. 9, Shahid Behtoui St,
Before 45-meter Kaj, Estiklal Blvd, Azimieh, Karaj

City

Karaj

Province

Alborz

Postal code

3154694763

Phone

+98 26 3250 7699

Email

Mostafakal1375@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Alireza Dehghan Nayeri

Position

Assistant Professor of Cardiology

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

School of Medicine, Alborz University of Medical Sciences Campus, Above Art University, End of West Bouali, Nobovat Sq, Karaj

City

Karaj

Province

Alborz

Postal code

3149969415

Phone

+98 26 3419 8000

Email

ama_dehghan@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mostafa Kalvandi

Position

Cardiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

Unit 3, Sayeh Building, No. 9, Shahid Behtoui St,

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

To protect patient confidentiality and privacy and in accordance with the ethical and legal regulations of Alborz University of Medical Sciences individual participant data will not be publicly shared and study findings will only be published as aggregate data in scientific journals

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available