Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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

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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
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Sponsors / Funding sources

1

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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
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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