Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Effect of Sildenafil on Ischemic Cardiac Clinical and paraclinical manifestations in patients with Coronary Slow Flow Phenomenon : a randomized controlled clinical trial

Protocol summary

Study aim
Determination of the effect of sildenafil on the clinical manifestations of myocardial ischemia in patients with coronary slow flow

Design
Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 2 on 20 patients

Settings and conduct
10 patients with slow coronary blood flow in Afshar Hospital in Yazd will be prescribed sildenafil for 3 months and we will study the effects of this drug on improving patients' heart symptoms and changes in their ETT

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definitive diagnosis of CSFP on coronary angiography ;Clinical signs of ischemia include typical angina pectoris or dyspnea. Exclusion criteria: Patients with myocardial infarction or PCI or CABG or valve replacement or repair; Patients with Obstructive CAD (stenosis greater than 40%); Patients with hepatic or renal insufficiency or CVA or COPD or Cancer or acute infectious disease such as Covid 19; Patients older than 70 years or less than 30 years; Patients with low systolic blood pressure (less than 90 mmHg); Patients with severe uncontrolled hypertension (more than 180/100); Patients with aneurysm or ectasia or no-reflow or spasm or dissection or systolic heart failure or valvular disease; Patients with LVEF less than 50%

Intervention groups
Sildenafil will be prescribed to half of the patients, the treatment will start with a daily dose of 50 mg orally and will continue for 12 weeks. In the other half of the patients who are in the control group, like the intervention group, placebo medicine is prescribed instead of sildenafil tablets.

Main outcome variables
Clinical symptoms,ETT changes,readmission rate

General information

Reason for update
Completion of information on the exact date of enrollment and Changing the drug administration method from 25 mg twice a day to 50 mg daily

Acronym

IRCT registration information
IRCT registration number: **IRCT20220223054103N1**
Registration date: **2022-04-28, 1401/02/08**
Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**
Update count: **1**

Registration date
2022-04-28, 1401/02/08

Registrant information

Name
Amin Entezari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3834 7651

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2022-10-23, 1401/08/01

Actual recruitment start date
2022-06-26, 1401/04/05

Actual recruitment end date

2022-09-19, 1401/06/28

Trial completion date

2022-12-19, 1401/09/28

Scientific title

Effect of Sildenafil on Ischemic Cardiac Clinical and paraclinical manifestations in patients with Coronary Slow Flow Phenomenon : a randomized controlled clinical trial

Public title

Effect of Sildenafil on Coronary Slow Flow Phenomenon

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with definitive diagnosis of CSFP on coronary angiography. Patients with clinical signs of ischemia including typical angina pectoris (at least 2-3 minutes retrosternal and compressive angina) or dyspnea (equivalent to angina).

Exclusion criteria:

Patients with myocardial infarction or PCI or CABG or valve replacement or valve repair Patients with Obstructive CAD (stenoses greater than 40%) Patients with hepatic or renal failure or CVA or COPD or Cancer or acute infectious disease such as Covid 19 Patients older than 75 years or less than 30 years Patients with low systolic blood pressure (<90 mmHg) Patients with severe uncontrolled hypertension (> 180/100) Patients with LVEF <50%

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done based on the quadruple block method.The letters A and B will be used to assign the drug and the placebo. Until the drug is assigned, it will not be clear which A and B belong to the drug or the placebo. Only one person (the main executor) is aware. For concealment, the person who performs the randomization and specifies the following arrangements (AABB ,ABAB, ABBA, BBAA, BABA, BAAB) will be different from the person delivering the drug to the patient.For randomization, random order of 4 is noted and each block is placed in a sealed envelope. After registering all the patients, each patient is given a code. After the blocks are randomized, the randomized sequences are numbered sequentially. The person who allocates the drug assigns the prepared drugs to the patient after opening each envelope.

Blinding (investigator's opinion)

Triple blinded

Blinding description

A person who is aware of the assignment of the letters A and B to a drug or placebo is only the first executor and project manager. Other people who do randomization and drug allocation and examination and evaluation of patient outcomes and statistical analysis are different people and do not know which letter is assigned to the drug or placebo.The drugs are available to the dispenser in the same form in completely similar packages, and the patient himself is also unaware that he is receiving the drug or placebo. The drug packages are unnamed and are only in boxes A and B. The dispenser and the doctor are not aware of the contents of boxes A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Shahid Sadoughi Blvd

City

Yazd

Province

Yazd

Postal code

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Approval date

2022-04-04, 1401/01/15

Ethics committee reference number

ssu.rec.1401.002

Health conditions studied

1

Description of health condition studied

Coronary Slow Flow Phenomenon

ICD-10 code

I25.118

ICD-10 code description

Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris

Primary outcomes

1

Description
Chest Pain according to Canadian cardiovascular society classification
Timepoint
Begining of the study, 1 , 2 , 3 months after taking sildenafil
Method of measurement
Canadian cardiovascular society classification questionnaire

2

Description
Duke treadmill score
Timepoint
Begining of the study, 3 months after taking sildenafil or placebo
Method of measurement
Scoring based on the Duke treadmill score

3

Description
Functional capacity in exercise treadmill test
Timepoint
Begining of the study, 3 months after taking sildenafil or placebo
Method of measurement
Achived METs

Secondary outcomes

1

Description
ETT changes
Timepoint
begining of the study and 3 months later
Method of measurement
exercise treadmill test

2

Description
blood pressure
Timepoint
begining of the study and 1 and 2 and 3 months later
Method of measurement
Blood pressure monitor

Intervention groups

1

Description
Intervention group: The use of Sildenafil starts with a daily dose of 50 mg orally and continues for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: The placebo is started once daily orally and continues like the intervention group until the end of the study.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Afshar Hospital
Full name of responsible person
Amin Entezari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
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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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Amin Entezari

Position
M.D, Specialist

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable