

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The short-term effect of lorazepam on the anxiety level of ST Elevation Myocardial Infarction (STEMI) patients candidate for Primary Percutaneous Coronary Intervention (PPCI)

Protocol summary

Study aim

Determination of the short-term effects of lorazepam in ST Elevation Myocardial Infarction patients candidate Primary Percutaneous Coronary Intervention.

Design

A double blind clinical trial with 2 groups: intervention and control groups with 140 STEMI patients candidates for PPCI. Patients are randomly divided into two groups using sas software. In phase 2, in one group 70 people receive Lorazepam and the other group 70 people receive a placebo.

Settings and conduct

In this study, patients referred to Buali Sina Hospital in Qazvin with acute MI symptoms diagnosed with an ECG and troponin check, candidates for PPCI by a cardiologist, will be included. After giving the necessary explanations, informed consent is taken from the patients. patients will consume the contents of the medicine package 30 minutes before PPCI. On the first visit in the ward after PPCI, the anxiety level of the patients is assessed using the Hospital Anxiety and Depression Scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. ST Elevation Myocardial Infarction 2. Primary Percutaneous Coronary Intervention candidate 3. From 18 to 80 years old Exclusion criteria: 1. Drug interactions: Alcohol; Barbiturates; Antipsychotics; Sedative/hypnotics; Anxiolytics; Opioids; Antidepressants; Narcotic analgesics; Sedative antihistamines; Anticonvulsants; Anesthetics 2. Contraindications for lorazepam prescription: Drug allergies; Acute angle closure glaucoma; Severe respiratory depression 3. Unconsciousness

Intervention groups

Intervention group: Patients receive a Lorazepam tablet half an hour before Primary Percutaneous Coronary Intervention. Control group: patients receive a placebo half an hour before Primary Percutaneous Coronary

Intervention.

Main outcome variables

Patients anxiety, procedure time, Primary and Secondary thrombolysis in myocardial infarction(TIMI) flow, Heart rate, QT interval

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201102049232N3**

Registration date: **2023-01-10, 1401/10/20**

Registration timing: **prospective**

Last update: **2023-01-10, 1401/10/20**

Update count: **0**

Registration date

2023-01-10, 1401/10/20

Registrant information

Name

Ali Pazoki

Name of organization / entity

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Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The short-term effect of lorazepam on the anxiety level of ST Elevation Myocardial Infarction (STEMI) patients candidate for Primary Percutaneous Coronary Intervention (PPCI)

Public title

The effect of Lorazepam on the anxiety of heart attack patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

ST Elevation Myocardial Infarction (STEMI) patients candidate for Primary Percutaneous Coronary Intervention (PPCI)

Exclusion criteria:

Patients who cannot take lorazepam because of Drug interactions, including alcohol; barbiturates; antipsychotics sedatives; hypnotics; anxiolytics; opioids; antidepressants; narcotics; analgesics; sedatives; antihistamines; anticonvulsants and anesthetics. Patients who cannot take lorazepam because of lorazepam Contraindications including Allergy to Lorazepam; acute angle; closure glaucoma; severe respiratory depression and sleep apnea Patients who cannot take lorazepam because of unconsciousness

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method will be done as available among patients. In the next step, the samples will be divided into two intervention and control groups in the form of blocked randomization. Blocking and sequencing of samples will be done with random allocation software. In order to conceal the random allocation process, the names of the groups are placed in envelopes, these envelopes are numbered from 1 to 140 and arranged in a box in; the researcher who performs the random allocation wont be aware of the contents of the envelopes. The contents of the envelopes indicate the

study groups (intervention or placebo) and after making sure that the sample enters the research and obtaining written consent, the first envelope is taken in order of number and according to the contents of the envelope and is placed in one of the Study groups are placed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients, the researcher, the data collector and the outcome examiner, and the healthcare personnel will be unaware of the intervention and control groups. Lorazepam and placebo drug packages will be prepared and will be placed in the emergency room of the hospital without specifying its drug content. Medication packages are prepared by a separate pharmacist. On each package, a special code for the type of drug will be specified, and its content is specified in the study database.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar boulevard, Ethics committee of Qazvin University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

59811-34197

Approval date

2022-12-17, 1401/09/26

Ethics committee reference number

IR.QUMS.REC.1401.259

Health conditions studied**1****Description of health condition studied**

STEMI

ICD-10 code

I21.3

ICD-10 code description

ST elevation (STEMI) myocardial infarction of unspecified site

2

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

anxiety

Timepoint

First ward visit after Primary Percutaneous Coronary Intervention (PPCI)

Method of measurement

Hospital Anxiety and Depression Scale (HADS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group receive a single dose of 1 mg/dl lorazepam from Kimidaro pharmaceutical company half an hour before Primary Percutaneous Coronary Intervention (PPCI) and after the PPCI their anxiety levels will be assessed.

Category

Treatment - Drugs

2

Description

Control group: They are the group that receives a single dose of placebo containing microcrystalline cellulose and magnesium acetate from Alborz Daru company half an hour before primary Percutaneous Coronary Intervention (PPCI) and after the PPCI their anxiety levels will be assessed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bou Ali Sina Hospital

Full name of responsible person

Kimia Rahimi Ardali

Street address

Bou Ali Street, Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mahdi Mirhashemi

Street address

Vice-Chancellor's Office for Research and Technology Affairs, Qazvin University of Medical Sciences, Shahid Beheshti Avenue

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Ali Pazoki

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Kimia Rahimi Ardali

Position

دانشجو

Latest degree

A Level or less

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Academic and scientific researchers and Industries

Under which criteria data/document could be used

Permission is granted to use the data for meta-analysis or to design other studies

From where data/document is obtainableSubmit request via email dralipazoki@gmail.com
a.pazoki@qums.ac.ir**What processes are involved for a request to access data/document**

If the applicant submits a request, if 6 months have passed since the publication of the article, it will be answered in less than 1 week.

Comments