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

Country

Iran (Islamic Republic of)

Phone

+98 28 3332 6034

Email address

a.pazoki@qums.ac.ir

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
City
Qazvin
Province
Qazvin
Postal code
3413786165
Phone
+98 28 3332 6033
Email
dralipazoki@gmail.com

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
City
Qazvin
Province
Qazvin
Postal code
34199-15315
Phone
+98 28 3333 7006
Email
sm.mirhashemi@qums.ac.ir
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
Street address
Secretariat, Bouali Hospital, Bouali Street
City
Qazvin
Province
Qazvin
Postal code
3413786165
Phone
+98 28 3332 6034
Email
a.pazoki@qums.ac.ir

Person responsible for scientific 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
Street address
Secretariat, Bouali Hospital, Bouali Street
City
Qazvin
Province
Qazvin
Postal code
3413786165
Phone
+98 28 3332 6034
Email
a.pazoki@qums.ac.ir

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
Other areas of specialty/work
General Practitioner
Street address
Bou Ali Sina Hospital, Bou Ali Street
City
Qazvin
Province
Qazvin
Postal code
3413786165
Phone
+98 28 3332 6032
Email
kimiarahimiardali@gmail.com

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 obtainable
Submit 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