

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of the effect of tizanidine administration on acute pain control after CABG in adult patients: A randomized placebo-controlled clinical trial

Protocol summary

Study aim

In this study, we will investigate the effect of tizanidine on acute pain control after coronary artery bypass graft (CABG) surgery in adult patients admitted to Imam Reza Hospital.

Design

This phase 3 double-blind clinical trial will be performed on 60 adult patients. The random number table method will be used to randomize and divide patients into two groups of intervention and control.

Settings and conduct

This clinical trial will be performed in the intensive care unit of Imam Reza Hospital. An equal number of patients will be admitted to the intervention and control groups by simple randomization. In this study, participants, researchers, clinical caregivers, and data analysts were considered blind. Another expert who is not involved in prescribing, evaluating treatment, or analyzing data, will assign patients to study groups.

Participants/Inclusion and exclusion criteria

Admission requirements: Patients admitted to CABG surgery in the age range of 18 to 65 years receiving standard medication regimen Signing the informed consent form by the patient Conditions for not entering the study: Severe renal failure (CrCl <25 ml/min) History of drug or alcohol addiction Low arterial blood pressure (SBP <90 mmHg or MAP <65 mmHg) Concomitant use of dexmedetomidine Taking painkillers 24 hours before surgery

Intervention groups

Patients admitted to the intervention group receive one 4 mg tizanidine tablet immediately before surgery and then twice daily until the end of the second day after surgery. In the control group, patients receive a placebo tablet that looked exactly like the original drug immediately before surgery and then instructed twice a day until the end of the second day after surgery.

Main outcome variables

The severity of postoperative pain with the use of Numerical Rating Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201220049774N1**

Registration date: **2020-12-28, 1399/10/08**

Registration timing: **prospective**

Last update: **2020-12-28, 1399/10/08**

Update count: **0**

Registration date

2020-12-28, 1399/10/08

Registrant information

Name

Hesamoddin Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1586

Email address

hosseinih@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-13, 1399/11/25

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of tizanidine administration on acute pain control after CABG in adult patients: A randomized placebo-controlled clinical trial

Public title

Effect of tizanidine on pain after cardiac surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients hospitalized for CABG surgery in the age range of 18 to 65 years receiving standard medication regimen (Aspirin, P2Y12 platelet receptor blockers, angiotensin-converting enzyme inhibitors, beta-blockers, and statins) Signing the informed consent form by the patient

Exclusion criteria:

severe renal failure (CrCl <25 ml/min) Severe hepatic impairment (patients with class C hepatic impairment based on Child-Pugh classification with a score of 10-15 based on the parameters of ascites, bilirubin, albumin, INR and encephalopathy) History of hypersensitivity reactions to tizanidine History of drug or alcohol addiction Low arterial blood pressure (SBP <90 mmHg or MAP <65 mmHg) Concomitant use of dexmedetomidine Chronic pain Taking painkillers 24 hours before surgery Neuromuscular disease Class IV (severe) heart failure according to the New York Heart Association classification Receiving ciprofloxacin during hospitalization Pregnancy or breastfeeding

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The random number table method will be used for simple randomization and division of patients into two groups of intervention and control and determining the type of drug received (drug or placebo). The table for assigning each code to each patient is provided for the expert in the center for prescribing and rational use of drugs in Imam Reza (AS) Hospital. It should be noted that the expert is fully aware of the type of code (Knows what medication each patient has received. Also, medications

are given to him or her based on the number (A or B), and he or she is fully aware of which code is related to drug or placebo). The expert is not involved in prescribing or evaluating the treatment or analyzing the data and is solely responsible for maintaining the codes and assigning patients to one of the relevant codes. Adult patients who are candidates for CABG surgery are randomly assigned to one of the groups by the expert according to the codes set. The drug or placebo tablets are then given to the researcher who is unaware of codes and the content of tablets.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants, the lead researcher in charge of data collection and outcome assessment, clinical caregivers, including physicians and nurses, and data analysts, were considered blind to the study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Mashhad University of Medical Sciences

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Ferdowsi University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Approval date

2020-12-19, 1399/09/29

Ethics committee reference number

IR.MUMS.REC.1399.535

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

Coronary Artery Disease

ICD-10 code

I20/ I21

ICD-10 code description

Chapter IX / Diseases of the circulatory system (I00-I99) / I20 Angina pectoris/ I21 Acute myocardial infarction

Primary outcomes

1

Description

The severity of postoperative pain with the use of Numerical Rating Scale

Timepoint

The severity of postoperative pain is measured in the intensive care unit after the end of surgery and on days first and second postoperative, two hours after the administration of 4 mg tizanidine tablet.

Method of measurement

Numerical Rating Scale

Secondary outcomes

1

Description

Systolic blood pressure and mean arterial pressure

Timepoint

It is measured before surgery, during surgery, and after the patient enters the intensive care unit and in the first and second days after surgery twice in two hours after administration of 4 mg tizanidine tablets.

Method of measurement

Cardiac monitoring device

2

Description

Heart rate

Timepoint

It is measured before surgery, during surgery, and after the patient enters the intensive care unit and in the first and second days after surgery twice in two hours after administration of 4 mg tizanidine tablets.

Method of measurement

Cardiac monitoring device

3

Description

Drowsiness

Timepoint

It is measured before surgery, and after the patient enters the intensive care unit and in the first and second days after surgery twice in two hours after administration of 4 mg tizanidine tablets.

Method of measurement

Kulka four-level criterion

4

Description

Dry mouth

Timepoint

It is measured before surgery, and after the patient enters the intensive care unit and in the first and second days after surgery twice in two hours after administration of 4 mg tizanidine tablets.

Method of measurement

Question from the patient

5

Description

Total amount of narcotic drug used

Timepoint

It is calculated during the patient monitoring from the end of surgery to the end of the second day after surgery.

Method of measurement

Patient nursing care cardex

6

Description

Time of administration of the first dose of narcotic analgesic after surgery in the intensive care unit

Timepoint

Calculated in minutes from the time of completion of surgery.

Method of measurement

Patient nursing care cardex

7

Description

Total number of times of prescribing fixed-dose narcotic analgesic

Timepoint

It is calculated during the patient monitoring from the end of surgery to the end of the second day after surgery.

Method of measurement

Patient nursing care cardex

Intervention groups

1

Description

Intervention group: Patients admitted to the intervention group take one 4 mg tizanidine tablet with 30 to 50 cc of water immediately before surgery. After the admission of post CABG surgery patients to the intensive care unit, tizanidine tablets are prescribed to patients at a dose of 4 mg twice a day until the end of the second day after surgery.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group, take a placebo tablet that looked exactly like the original drug with 30 to 50 cc of water immediately before surgery. After the admission of post CABG surgery patients to the intensive care unit, placebo tablets are prescribed to patients at a dose of 4 mg twice a day until the end of the second day after surgery.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Hesamoddin Hosseini

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Imam Reza Educational, Research and Treatment Center, Imam Reza Square, Ibn-e Sina Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology

Street address

University Street, next to Hoveyeh Cinema, Ghoreishi Building, Deputy of Research and Technology

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hesamoddin Hosseini

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Razavi Khorasan

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

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