Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Benson's relaxation on range of headache-induced by intravenous infusion of nitroglycerin in acute coronary syndrome patients

Protocol summary

Study aim
Determining the effect of Benson sedation on the severity of headache caused by intravenous nitroglycerin infusion.

Design
The present study is a parallel-group randomized controlled clinical trial. Eligible patients are divided into two groups of 30: intervention and control.

Settings and conduct
For the intervention group, the relaxation method will be performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: A new diagnosis of ACS, Age above 18 years, No migraine headaches and any other headaches, No drug addiction, Absence of neurological disorders under drug treatment, Absence of headache before starting nitroglycerin injection, Absence of pain in other parts of the body (except chest pain),Absence of speech and vision disorders, Not using oral and topical nitrate drugs Exclusion criteria: Non-cooperation due to increased chest pain and worsening of the patient's hemodynamic symptoms, need to increase the dose of nitroglycerin (more than 5 micrograms per minute), and non-cooperation with the researcher.

Intervention groups
For the intervention group, the relaxation method will be performed. This intervention will be performed after 5 minutes of teaching the patient how to do deep breathing for 15 minutes in the presence and with the help of a nurse. Intravenous nitroglycerin infusion will be performed at a dose of 5 micrograms per minute and a rate of 6 drops per minute.

Main outcome variables
Benson's Relaxation Headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110906007494N47**
Registration date: **2025-05-14, 1404/02/24**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-14, 1404/02/24**
Update count: **0**

Registration date
2025-05-14, 1404/02/24

Registrant information

Name
Masoumeh Bagheri Nesami

Name of organization / entity
Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-25, 1404/01/05

Expected recruitment end date
2025-06-26, 1404/04/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Benson's relaxation on range of headache-induced by intravenous infusion of nitroglycerin in acute coronary syndrome patients

Public title
Effect of Benson's sedation on nitroglycerin-induced headache
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A new diagnosis of ACS Age above 18 years No migraine headaches and any other headaches No drug addiction Absence of neurological disorders under drug treatment Absence of headache before starting nitroglycerin injection Absence of pain in other parts of the body (except chest pain) Absence of speech and vision disorders Not using oral and topical nitrate drugs
Exclusion criteria:
Lack of ability due to increased chest pain and confusion of the patient's hemodynamic symptoms (sbp<100, p<60) The need to increase the dose of nitroglycerin received (more than 5 micrograms per minute) Lack of cooperation with the researcher
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is done in an accessible manner. And based on statistical software, permuted block randomization method, random allocation is done in each group and 15 blocks of 4 are designed. So that 2 cards A and 2 cards B are placed in each block. 60 envelopes with lids with numbers 1-60 are inserted. A and B cards are placed inside the envelopes based on the numbers of the software, and based on the date of admission of the patients to the department, the envelopes are opened in order of number and the patients enter the study.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square. , Sari, Mazandaran, Iran.
City
Sari
Province
Mazandaran
Postal code
4816715793
Approval date
2025-01-01, 1403/10/12
Ethics committee reference number
IR.MAZUMS.REC.1403.490

Health conditions studied

1

Description of health condition studied
Acute Coronary Syndrome
ICD-10 code
I24.0
ICD-10 code description
Acute coronary thrombosis not resulting in myocardial infarction

Primary outcomes

1

Description
Pain
Timepoint
For both the intervention and control groups, The first headache measurement will be done 15 minutes after the start of intravenous nitroglycerin infusion (before the intervention). The second measurement of headache will be done 35 minutes after the start of intravenous nitroglycerin infusion (immediately after the end of sedation) and the third measurement of headache will be done 60 minutes after the start of intravenous nitroglycerin infusion (after the intervention).
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the intervention group, the sedation method will be performed by the researcher on the bed in Fatemeh Zahra Hospital in Sari. This intervention will be performed for 15 minutes in the presence and with the help of a nurse after 5 minutes of

teaching the patient how to take deep breaths. (After 15 minutes of starting the nitroglycerin infusion, 5 minutes of deep breathing training will be given, in other words, the intervention will be performed 20 minutes after starting the intravenous nitroglycerin infusion.) Intravenous nitroglycerin infusion will be performed at a dose of 5 micrograms per minute and a rate of 6 drops per minute (27); so that the intervention group will receive sedation despite the standard treatment (injection of one gram of intravenous acetaminophen or Apotel) (9).

Category

Treatment - Other

2

Description

Control group: The control group will receive the same dose of 5 micrograms per minute intravenous nitroglycerin infusion and, in the event of headache, the same protocol for treating headache caused by intravenous nitroglycerin infusion, which is an intravenous injection of 1 gram of acetaminophen, will be used (9); however, they will not receive any sedative intervention. Headache measurements in the control group will be performed similarly to those in the intervention group at 15, 35, and 60 minutes after the start of the intravenous nitroglycerin infusion.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra Hospital

Full name of responsible person

Masoumeh Bagheri Nessami

Street address

Moalem street

City

Sari

Province

Mazandaran

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48157-33971

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Professor Ahmad Ali Enayati

Street address

Mazandaran University of Medical Sciences,Valiye asar highway , Joybar 3 way ,Imam sq

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Mazandaran Mideacal Science

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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Masoumeh Bagheri Nesami

Position

PhD in Nursing Education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific

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Position
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Latest degree
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Nursery

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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
There is no further information

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