Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of midazolam in controlling uncomplicated hypertension in patients presenting to the emergency department: a randomized, double-blind clinical trial study

Protocol summary

Study aim
Determining the level of control of uncomplicated high blood pressure, the overall length of patient stay, and the level of patient satisfaction with treatment in patients referred to the emergency department.

Design
A randomized, double-blind, parallel-group, controlled clinical trial on 142 patients. Random Allocation Software version 1.0.0 was used for randomization

Settings and conduct
The rate of midazolam and placebo will be administered as a slow intravenous injection over one minute with vital signs monitored including finger pulse oximetry to check heart rate and arterial blood oxygen level. The patient will then be prescribed the required medications based on the case or control group, and systolic and diastolic blood pressure and mean arterial blood pressure will be recorded at 15-30-45-60 minutes after administration, and the rate of change will be calculated from 0 to 60 minutes. The length of stay in the emergency department will be recorded i. Patient satisfaction will be recorded at the end of the treatment period using the VAS (visual analog scale) in the emergency department.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients over 18 years of age who complain of symptoms related to hypertensive crisis, are conscious, and consent to participate in the study. Patients who leave the study before completing it and obtaining final results during hospitalization will be excluded from the study.

Intervention groups
Patients will be randomly assigned to two groups: case (midazolam + captopril group) and control (captopril treatment). In the case group, patients will receive captopril 25 mg orally + midazolam 0.02 mg/kg body weight intravenously (sedation dose) (18). In the control group, patients will receive captopril 25 mg + distilled water 0.02 mg/kg body weight intravenously.

Main outcome variables
HTN control Length of stay Satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260306068968N1**
Registration date: **2026-04-25, 1405/02/05**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-25, 1405/02/05**
Update count: **0**

Registration date
2026-04-25, 1405/02/05

Registrant information

Name
Fatemeh Sadeghi chorsi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-04-21, 1405/02/01

Expected recruitment end date
2028-04-20, 1407/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of midazolam in controlling uncomplicated hypertension in patients presenting to the emergency department: a randomized, double-blind clinical trial study

Public title
Evaluation of the effect of midazolam in controlling uncomplicated hypertension in patients presenting to the emergency department
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
hypertension crisis contious
Exclusion criteria:
End organ damage Pregnant women
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **142**
Randomization (investigator's opinion)
Randomized
Randomization description
patients will divided with computer randomization (random Allocation Software version 1.0.0) to two blockes, which are discribed as case group (group with Midazolam and Captopril) and control Group (captopril).
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding in this study will be designed as follows : Midazolam and placebo will be prepared in identical forms (in similar numbered syringes) by the principal investigator. To ensure allocation concealment, the sequentially numbered container method will be used.The medication containers will be pre-prepared and sequentially numbered in advance to prevent manipulation. The numbers will be assigned according to a computer-generated randomization program (output file attached) , from number 1 to 142. These will be provided swquentiallty , as needed , to the resident responsible for the thesis, and will be administered to patients according to the order of patient admission and enrollment in the emergency department.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz university of medical sciences
Street address
Golgasht street, Tabriz University of medical sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Approval date
2026-02-18, 1404/11/29
Ethics committee reference number
IR.TBZMED.REC.1404.827

Health conditions studied

1

Description of health condition studied
Hypertension
ICD-10 code
10
ICD-10 code description
فشارخون

Primary outcomes

1

Description
Blood pressure control
Timepoint
At baseline, and at 15 , 30 , 45 , and 60 minutes after initation of treatment.
Method of measurement
Blood pressure monitor

Secondary outcomes

1

Description
patient satisfaction with the treatment
Timepoint
15 - 30 - 45 - 60 minutes
Method of measurement
digital wristwatch for time measurement

Intervention groups

1

Description
Intervention group:
Category
Treatment - Drugs

2

Description
Control group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Fatemeh Sadeghi chorsi
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Sponsors / Funding sources

1

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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
Tabriz 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
Tabriz University of Medical Sciences
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asghar jafari rouhi
Position
assistant professor
Latest degree
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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
Yes - There is 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
Yes - There is 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
Data will be shared after being de-identified.
When the data will become available and for how long
Data will be uploaded after 6 months of publication.
To whom data/document is available
All researchers
Under which criteria data/document could be used
Can be used in all research with citation of the source.
From where data/document is obtainable
Accessible by email.
What processes are involved for a request to access data/document
Within one week of receiving the request
Comments