

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Efficacy of midazolam on blood pressure control in patients attending to emergency ward with hypertension crisis

#### Protocol summary

##### Study aim

Determine the effectiveness of midazolam in blood pressure control in patients presenting to the emergency department with a diagnosis of hypertensive crisis

##### Design

If the code in envelope A is patient with captopril and distilled water, if the code is B, it is a medication called Midazolam and a placebo of vitamin B, and if the code C is given, then Midazolam and Captopril will be prescribed.

##### Settings and conduct

This is a triple-blind clinical trial that will be performed on hypertensive patients referred to Emergency Hospital of Imam Hossein Shahroud Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: systolic or diastolic blood pressure above 180 on 110 mm Hg, the age group of 80-18 years, have the power to understand and sign an informed consent. Exclusion criteria: Acute left heart failure, Chronic renal failure, cardiovascular disease, History of stroke, History of myocardial infarction, Benzodiazepines consumed in the last week, Use muscle relaxants such as baclofen or anti-anxiety drugs, Other groups such as Zolpidem or Buspirone, Captopril susceptibility, Sensitivity to midazolam, Pregnant and lactating women, The occurrence of a critical condition, according to the doctor's opinion, requires the administration of a low blood pressure medication other than midazolam and captopril. Patients with a difference between the two arms are more than 15 mm Hg.

##### Intervention groups

This study is randomly divided into three groups of 43 people. The two main drug captopril sublingual orally (25 mg) and midazolam intravenous injection (1 mg) will take place. Two placebos will be used in this program, which includes oral pills of vitamin B instead of captopril and distilled water instead of midazolam. After obtaining informed consent, patients will be randomly divided into three groups according to the order of the envelope.

#### Main outcome variables

hypertension

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181010041299N1**

Registration date: **2018-12-08, 1397/09/17**

Registration timing: **prospective**

Last update: **2018-12-08, 1397/09/17**

Update count: **0**

##### Registration date

2018-12-08, 1397/09/17

##### Registrant information

##### Name

mostafa enayatrad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3239 3961

##### Email address

mostafaenayatrad@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-11, 1397/09/20

##### Expected recruitment end date

2019-05-10, 1398/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Efficacy of midazolam on blood pressure control in patients attending to emergency ward with hypertension crisis

**Public title**

Efficacy of midazolam on blood pressure control

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

Systolic or diastolic blood pressure above 180 on 110 mm Hg age group is 18-18 years old Have the power to understand and sign a conscientious informed consent

**Exclusion criteria:**

Chronic renal failure Cardiovascular disease History of stroke History of myocardial infarction Benzodiazepines consumed in the last week Use of muscle relaxants such as baclofen or anti-anxiety drugs Other groups such as zolpidum or bupropion Acute left heart failure Captopril susceptibility Sensitivity to midazolam Sensitivity to midazolam Pregnant and lactating women The occurrence of a critical condition, according to the doctor's opinion, requires the administration of a blood pressure lowering medication other than midazolam and captopril Patients with a difference between the two arms are more than 15 mm Hg

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **129**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were randomly assigned to three groups of 43 individuals using Random allocation software and from the first patient who has met criteria for the allocation of treatments based on randomization, everyone is treated with their medication.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Participant: The use of placebo in addition to the current drug was administered in a group of captopril tablets and placebo, distilled water, and in the second group, the drug was injected with midazolam and vitamin B tablets, and in the third group of captopril tablets and midazolam injectable drug. Outcome evaluator: The blood pressure meter will be measured before and after the intervention by the nurse present in the shift, who is unaware of how

the medications are allocated to the patient. DATA ANALYSIS: No information is available on how to allocate drugs to the groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Shahroud University of Medical Sciences

**Street address**

Room 409. Third floor. medical School. Shahroud University of Medical Sciences. Hafte-Tir Square. Tehran Avenue. Shahroud. Ira

**City**

Shahroud

**Province**

Semnan

**Postal code**

3614773947

**Approval date**

2018-07-24, 1397/05/02

**Ethics committee reference number**

IR.SHMU.REC.1397.076

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

Crease blood pressure

**ICD-10 code**

I10

**ICD-10 code description**

Essential (primary) hypertension

**Primary outcomes****1****Description**

Systolic or diastolic blood pressure

**Timepoint**

Blood pressure measurement at the beginning of the study and 10 minutes after (before the intervention). Then at 15, 30, 45 and 60 minutes after the intervention

**Method of measurement**

How to measure blood pressure in a standardized manner using a mercurial barometric device.

## Secondary outcomes

### 1

#### Description

Sleepiness rate

#### Timepoint

15, 30, 45 and 60 minutes after intervention

#### Method of measurement

Examination by a specialist

### 2

#### Description

Shortness of breath

#### Timepoint

15, 30, 45 and 60 minutes after intervention

#### Method of measurement

Examination by a specialist

## Intervention groups

### 1

#### Description

Intervention group 1: Intravenous Midazolam injection of 1 mg and placebo vitamin B tablets

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: intravenous Midazolam injection of 1 mg and Captopril 25 mg

#### Category

Treatment - Drugs

### 3

#### Description

Control group 1: 25 mg captopril tablets and injected placebo distilled water

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Hossein Hospital, Shahroud, Semnan Province

##### Full name of responsible person

Dr. Mohammad Reza Khorsand Kemachali

##### Street address

Emergency department. Imam Hossein Hospital.  
Imam Hossein Square. Shahroud. Iran

##### City

Shahroud

##### Province

Semnan

#### Postal code

3614773947

#### Phone

+98 23 3239 5009

#### Email

a.noyani@shmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Hassan Emamian

##### Street address

Research Deputy. second floor. medical School.  
Shahroud University of Medical Sciences. Hafte-Tir  
Square. Tehran Avenue. Shahroud. Iran.

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3614773947

##### Phone

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##### Email

a.noyani@shmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Reza Khorsand Kemachali

##### Position

resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Emergency Medicine

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University of Medical Sciences. Hafte-Tir Square.  
Tehran Avenue. Shahroud. Iran.

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۳۶۱۴۷-۷۳۹۴۷

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**Email**

dr\_khorsandmd@yahoo.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Doctor Amir Noyani

**Position**

Supervisor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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a.noyani@shmu.ac.ir

## Person responsible for updating data

**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Mostafa Enayatrad

**Position**

Statistical Advisor

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

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**Phone**

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**Email**

mostafaenayatrad@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**

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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All collected data will be shared after being unidentifiable  
and analyzed

**When the data will become available and for how long**

By the end of 2019

**To whom data/document is available**

For all scholars

**Under which criteria data/document could be used**

For use in studies

**From where data/document is obtainable**

Supervisor

**What processes are involved for a request to access data/document**

By email and correspondence and justification for use

**Comments**