# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jul 2026

## Effect of Angiotensin-converting enzyme and β-blockers on the prognosis of patients with severely isolated brain trauma

## Protocol summary

**Study aim**
prognosis of severe isolated brain trauma
**Design**
Random function of Excel software based on patient file number will be used for randomization. Patients with severe brain trauma were included in the Excel program based on the file number and were divided into-2 groups case, control and control group based on the random button. There were three groups of 32 people in total. By entering the file number in Excel program, then the random number is selected from the data analysis command. This study has three groups that can be numbered from 1 to 3, respectively. It is clear that the repetition of each number occurs once in each group, so select the repeating each number option and select 32 for repeating the sequence. In this way, 96 units will be produced.
**Settings and conduct**
This study is a double-blind clinical trial, participants and researchers are not aware of the patient and drug groups.As the clinical caregiver administers the medication to the patient and the patient is unaware of the medication received.
**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Severe trauma, Age greater than or equal to 18 years, No previous use of beta-blockers at home, Informed consent of the patient's guardian, Satisfaction for the patient to enter the study Exclusion criteria: Death of the patient, Do not take other drugs that affect the sympathetic system, Renal artery stenosis, Chronic kidney disease, History of drug allergy, Hyperkalemia, High creatinine, Bradycardia
**Intervention groups**
Intervention group 1: Propranolol From Abidi Pharmacy :1 mg, injectable, in the first 24 hours up to two weeks Intervention group 2: Enalapril From Abidi Pharmacy:2.5 mg, gavage, in the first 24 hours after admission up to two weeks Control group: routine care
**Main outcome variables**
Glasgow Outcome Scale to measure level of consciousness

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20210514051289N1**
Registration date: **2022-05-08, 1401/02/18**
Registration timing: **retrospective**

Last update: **2022-05-08, 1401/02/18**
Update count: **0**
**Registration date**
2022-05-08, 1401/02/18

**Registrant information**
**Name**
Ahmad Sahraei
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2021-11-22, 1400/09/01
**Expected recruitment end date**
2022-02-20, 1400/12/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Effect of Angiotensin-converting enzyme and β-blockers on the prognosis of patients with severely isolated brain trauma

**Public title**
Effect of Angiotensin-converting enzyme and β-blockers on the prognosis of severe isolated brain trauma

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Severe trauma Age greater than or equal to 18 years No previous use of beta-blockers or Angiotensin-converting enzyme at home Informed consent of the patient's guardian or legal guardian to admit the patient to the study

**Exclusion criteria:**
Renal artery stenosis Chronic kidney disease History of drug allergy Hyperkalemia High creatinine Bradycardia or heart block

**Age**
From **18 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **96**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
This study is a double-blind clinical trial in which patients are randomly divided into three groups. Random function of Excel software based on patient file number will be used for randomization. Patients with severe trauma enter the Excel program based on the file number and were divided into - 2 groups case, and control group based on the random button. There were three groups of 32 people in total. By entering the file number in Excel program, then the random number is selected from the data analysis command. This study has three groups that can be numbered from 1 to 3, respectively. It is clear that the repetition of each number occurs once in each group, so select the repeating each number option and select 32 for repeating the sequence. In this way, 96 units will be produced.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
This study is a double-blind clinical trial in which patients are randomly divided into three groups. In this study, participants and researchers are not aware of which group the patient is in and which medication he is taking. As the clinical caregiver will take the medicine and the patient does not know what medicine he is taking.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Isfahan University of Medical Sciences

**Street address**
Isfahan University of Medical Sciences, Hezar Jerib St., Shiraz Gate

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673461

**Approval date**
2021-04-20, 1400/01/31

**Ethics committee reference number**
IR.MUI.MED.REC.1400.060

## Health conditions studied

### 1

**Description of health condition studied**
Severe isolated brain trauma

**ICD-10 code**
S06.2X

**ICD-10 code description**
Diffuse traumatic brain injury

## Primary outcomes

### 1

**Description**
Glasgow Outcome Score

**Timepoint**
Three months after the intervention

**Method of measurement**
Glasgow Outcome Scale to measure level of consciousness

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group1: Propranolol From abidi Pharmacy: The dose of 1 mg, injectable, starts in the first 24 hours after admission for patients in this group and continues until two weeks later. After transferring the patient from the intensive care unit to the ward and the ability to tolerate the drug, 40 mg of propranolol is administered as a pill every twelve hours orally.

**Category**
Treatment - Drugs

### 2

**Description**
Intervention group2: Enalapril From abidi Pharmacy. The dose of 2.5 mg, gavage, in the first 24 hours after admission for patients in this group (injectable form of this drug is not available in Iran)It continues until two weeks later. The goal is to maintain the patient's blood pressure between 160-100. If the pressure is not controlled, the dose can be increased to 5 mg every 12 hours. If the pressure drops below 100 mm Hg, the drug will hold.

**Category**
Treatment - Drugs

### 3

**Description**
Control group: This group receives only routine care after head trauma

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Kashani Hospital

**Full name of responsible person**
Mehdi Mahmoudkhani

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
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**Full name of responsible person**
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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**
Esfahan University of Medical Sciences

**Proportion provided by this source**
10

**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**
Esfahan University of Medical Sciences

**Full name of responsible person**
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**Position**
Assistant Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Neurosurgery

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## 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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable