Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Country
Iran (Islamic Republic of)
Phone
+98 31 3626 3127
Email address
ahmad.sant@gmail.com

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

Street address
Kashani hospital, Kashani St.,Isfahan,Iran

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3233 0091

Email
Kashanihospital@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjuye Javanmardi

Street address
Isfahan University of Medical Sciences, hezar jarib S.T

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 0048

Email
research@mui.ac.ir

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
Mehdi Mahmoudkhani

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

Street address
Isfahan University of Medical Sciences, Hezar Jarib St.,

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone

+98 31 3668 0048

Fax

Email

mahmoodkhani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Mahmoudkhani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

mahmoodkhani@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Sahraei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

ahmad.sant@gmail.com

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