

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effect of Propranolol on the Prognosis of Traumatic Brain Injury (TBI)

Protocol summary

Study aim

Determination of the Effect of Propranolol on the Prognosis of Traumatic Brain Injury

Design

Recruited patients will be divided into treatment and control group through simple randomization technique. This study is double blind and attending physician and patients are blind to treatment protocols. The patients in treatment group will be administered 20 mg propranolol, oral, twice a day. The control group will receive no intervention. Given a 95% confidence level, 80% power and a 10% attrition rate at least 110 samples are required.

Settings and conduct

In this study 110 patients admitted to Shahid Rajaee Trauma Center of Shiraz University Hospital with severe traumatic brain injury will prospectively be recruited. These patients will be divided into treatment and control group through simple randomization technique. This study will be double blind in which physician and patients are blind to treatment protocols.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age >18 years, blunt injury mechanism and admission to neurosurgical intensive care unit (NICU). Exclusion criteria: Early deaths (stay less<48 hours), patients prescribed beta-blocker therapy pre-admission and those suffering any extracranial injuries requiring invasive interventions or surgery

Intervention groups

The patients in treatment group will be administered 20 mg propranolol, oral, twice a day. The control group will receive no intervention.

Main outcome variables

Glasgow Outcome Score Extended (GOS-E)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130310012776N4**

Registration date: **2018-08-02, 1397/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-02, 1397/05/11**

Update count: **0**

Registration date

2018-08-02, 1397/05/11

Registrant information

Name

Hosseinali Khalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3625 4206

Email address

khalili_h@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-06, 1396/09/15

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Propranolol on the Prognosis of Traumatic Brain Injury (TBI)

Public title

effect of Propranolol in Traumatic Brain Injury (TBI)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age >18 years blunt brain injury mechanism admission to neurosurgical intensive care unit (NICU)

Exclusion criteria:

patients were prescribed regular beta-blocker therapy pre-admission those suffering any extracranial injuries requiring invasive interventions or surgery

Age

From **16 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization with randomizer software

Blinding (investigator's opinion)

Double blinded

Blinding description

ICU patients and attending Physician are unaware of treatment group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

6th Floor, Central building of Shiraz University of Medical Sciences, Zand St

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2017-11-05, 1396/08/14

Ethics committee reference number

IR.SUMS.REC.1396.133

Health conditions studied

1

Description of health condition studied

TBI

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Glasgow Outcome Score Extended (GOS-E)

Timepoint

6 months

Method of measurement

clinical exam

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 mg propranolol every 8 hours for 10 days.

Category

Treatment - Drugs

2

Description

control group: no drug use

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

Hosseinali Khalili

Street address

Rajaei Hospital, Chamran Blvd

City

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7194815711

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Hosseinali Khalili

Position

Associate 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

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

Informed Consent Form

Undecided - It is not yet known if there will be 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