

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Head Cooling and Remote Conditioning in Limb on outcome of patients with Traumatic Brain Injury

Protocol summary

Study aim

Determining the effect of head cooling and conditioning ischemia in patients with traumatic brain injury

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 84 patients.

Settings and conduct

A brain disorder caused by an external force applied to the head is known as a traumatic brain injury. Traumatic brain injuries are primary and secondary. Primary injury occurs immediately after the main injury and trauma, which includes bruising, damage to blood vessels, and axonal amputation, in which the axons of neurons are actually stretched or torn. Secondary injuries include damage to the blood-brain barrier, release of factors that lead to inflammation, overload of free radicals, excessive release of the neurotransmitter glutamate, entry of calcium and sodium ions into neurons, and mitochondrial dysfunction. The inflammatory response is initiated and controlled by a range of pre-inflammatory and anti-inflammatory cytokines, which are among the inseparable features of traumatic brain injury. Some studies have shown that interleukin-10 levels rise in severe traumatic brain injury. The level of alpha tumor necrosis factor in cerebrospinal fluid and serum of patients with traumatic brain injury increases. The usual clinical goal in traumatic brain injury is to reduce body temperature to normal.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age must be between 14 and 65 years and the Glasgow Coma Scale score of less than 8 ones are transferred to the intensive care unit. Exclusion criteria: drug dependence or history of cognitive impairment

Intervention groups

1) Head cooling group 2) RIC technique group 3) Head cooling group and RIC technique

Main outcome variables

Determining the average APACHE II scores in different

study groups before and after the study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210209050307N1**

Registration date: **2021-03-13, 1399/12/23**

Registration timing: **prospective**

Last update: **2021-03-13, 1399/12/23**

Update count: **0**

Registration date

2021-03-13, 1399/12/23

Registrant information

Name

Amir Moghadamahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2030-07-06, 1409/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Head Cooling and Remote Conditioning in Limb on outcome of patients with Traumatic Brain Injury

Public title

Effect of Head Cooling and Remote Conditioning in Traumatic Brain Injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Glawsco Coma Scale (GCS) score of less than 8

Exclusion criteria:

presence of known inflammatory disorder history of neurological or psychological disorders dependence to drugs or opium mild Traumatic Brain Injury (TBI) signs of disseminated injury without mass effect on brain Computed Tomography (CT) scan image

Age

From **14 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients enter the groups randomly after visiting the emergency department. Patients who enter the hospital consecutively enter the study groups in order. Randomization is block type and people enter the hospital in the first, second, third or fourth block, respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

After diagnosing the disease, the treating physician does not know the patient's entry into the desired group and the type of treatment, and also the patient has no information about the intervention and treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Emam Ali street

City

Rafsanjan

Province

Kerman

Postal code

7719794454

Approval date

2016-05-17, 1395/02/28

Ethics committee reference number

IR.RUMS.REC.1395.138

Health conditions studied

1

Description of health condition studied

Traumatic Brain Injury

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

APACHE II scores

Timepoint

72 hours -6 days- 2 months later

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: There is no intervention on them

Category

Diagnosis

2

Description

Intervention group 2: Head cooling group: Hypothermia caps are usually made of synthetic materials such as neoprene, silicone or polyurethane and are cooled with a cooling agent such as ice and gel that can be cooled to -25 to -30 degrees Celsius before use. For repeated use of the caps, they are filled with krillon gel, which freezes up to -30 degrees Celsius. As the caps warm up during

use, several ice caps are prepared, which must be replaced with a new, completely frozen ice cap every 20 to 30 minutes after use. In groups with ice caps, treatment is started immediately after admission. It is used for the first three consecutive days after admission for 0 to 6 hours (average 4.5 hours) depending on the patient's condition and tolerance to maintain the brain temperature at 33 to 34 degrees Celsius. The researcher measures the temperature of the brain with a tympanic membrane thermometer (the difference between the temperature of the tympanic membrane and the temperature of the brain is about 0.2 degrees Celsius). For this purpose, the brain temperature is likely to drop to about 33 to 34 degrees Celsius (it takes about 2 hours) and is maintained in the same range.

Category

Treatment - Devices

3

Description

Intervention group 3: RIC Technique Group: Arm ischemia is a full 5-minute full blood pressure cuff and a 5-minute empty blood pressure cuff in which the cuff is filled to 200 mm Hg or the patient's systolic pressure plus 25 mm Hg. This will be done at the same time as putting on the ice cap in the golden hours after the injury

Category

Treatment - Other

4

Description

Intervention group 4: Head cooling group and RIC technique

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abitaleb Hospital

Full name of responsible person

Fardin Hodoodi

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Ali Ibn Abitaleb Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan 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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Amir moghadamahmadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We are currently deciding to publish an article.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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