

# 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)

##### Phone

+98 34 3428 3328

##### Email address

a.moghadamahmadi@gmail.com

##### 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

##### Street address

Ali Ibn Abitaleb Square

##### City

Rafsanjan

##### Province

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##### Postal code

7719794454

##### Phone

+98 34 3428 0000

##### Email

fardin.neurosurgeon@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Ali Shamsizadeh

##### Street address

Abozar1/1

##### City

Rafsanjan

##### Province

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##### Postal code

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##### Phone

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##### Email

alishamsy@gmail.com

#### 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

Neurology

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**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