

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Clinical trial to compare the effect of cryopericriptate and conventional treatment on prevention of brain contusion expansion in trauma patients

Protocol summary

Study aim

Determination and evaluation of the effect of cryopericriptate on pervention of brain contusion expansion during the first 24 hours in traumatic patients.

Design

The randomized double blind clinical trial with two groups including intervention and control groups. Randomization is done through blocks with size of six and eight and online software. Sample size in each group is 25 patients.

Settings and conduct

Traumatic patients over 18 y/o and non_ pregnant who are brought to Kermanshah Talighani hospital and have brain contusion or intracerebral hemorrhage; after obtainlegal consent; will be divided into 2 groups. Patients themselves, planner and data collector do not know who is in the control and who is in the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: traumatic brain contusion or brain hematoma; over 18 years of age; their legal guardian allowance. Non-inclusion criteria: history of blood hemostatic factor deficiency; candidate for emergency brain hemorrhage surgery; pregnancy

Intervention groups

In the control group all standard measures including anticonvulsants , normal saline ,laboratory tests and thigh control of level of consciousness will be performed. In the intervention group four units of cryoprecipitate will be administered at the first time after confirmation of the diagnosis in addition to the standard treatments administered in the control group.

Main outcome variables

Intraparanchymal hematoma size of brain tissue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190729044375N1**

Registration date: **2021-01-31, 1399/11/12**

Registration timing: **prospective**

Last update: **2021-01-31, 1399/11/12**

Update count: **0**

Registration date

2021-01-31, 1399/11/12

Registrant information

Name

Alireza Tahmoures

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3836 7989

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-08, 1399/11/20

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to compare the effect of cryopericriptate and conventional treatment on prevention of brain contusion expansion in trauma patients

Public title

Effect of cryoprecipitate in trauma patients with brain contusion

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Traumatic brain contusion or brain hematoma Over 18 years of age Their legal guardian allowance

Exclusion criteria:

History of blood hemostatic factor deficiency Candidate for emergency brain hemorrhage surgery Pregnancy

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the block randomization method individuals are divided into two equal groups. Randomization process will be done using blocks of size 6 and 8. Blocking will already be done by random software online.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind_The physician who collects data, the physician who is responsible for patient care, the analyst and the patient included in the plan are unaware of who receives cryoprecipitate or or is in the control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medicine Sciences

Street address

Taleghani hospital; Shahid Beheshti boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847167

Approval date

2021-01-16, 1399/10/27

Ethics committee reference number

IR.KUMS.REC.1399.945

Health conditions studied**1****Description of health condition studied**

Brain contusion expansion in traumatic patients(ICH; IVH, Brain Contusion)

ICD-10 code

S06.3

ICD-10 code description

Focal traumatic brain injury

Primary outcomes**1****Description**

Size of brain tissue hematoma

Timepoint

At the time of admission and 6, 12, 24 and 48 hours after admission

Method of measurement

Size determination on CT scan graph by radiologist

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In addition to receiving conservative routine care; intravenous administration of 4 units of cryoprecipitate prepared in Iranian Blood Transfusion Organization which contains coagulation factors (fibrinogen& 8&13&VWF) in nonpregnant traumatic patient above 18y/o who have no history of blood factor deficiency disease.(routine and conservative care:ICU admission and control of GCS and anticonvulsant therapy)

Category

Treatment - Drugs

2**Description**

Control group:In this group patients with brain contusion due to trauma who are nonpregnant; above18y/o and have no history of blood factor deficiency disease are

only under routine conservative care(ICU admission and control of GCS and anticonvulsant therapy).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Taleghani hospital

Full name of responsible person

Dr.Mohammadreza Akrami

Street address

Shahid Beheshti boulevard

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alireza.tahmoures@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Kermanshah University of Medical Sciences

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Mohamamdreza Akrami

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Medical doctor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data collected in the research (including: age, gender, height, weight, lab.data and radiologic finding) can be shared after making people unidentifiable.

When the data will become available and for how long

Three months after announcement the results

To whom data/document is available

Only researchers working in academic institution

Under which criteria data/document could be used

This research will be done on limited number of people; but its results can be cited in meta_analyze.

From where data/document is obtainable

Dr. Mohamm Reza Akrami. Address: Department of neurosurgery; Taleghani hospital affiliated to Kermanshah University of Medical Sciences. Email address: mmdakramu@yahoo.com

What processes are involved for a request to access data/document

After confirming that the applicant has the conditions to receive the information (the researcher working in a university or scientific institute) the information will be provided to him/ her as soon as possible.

Comments