Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim
Determination and evaluation of the effect of cryopericipitate 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 ,laberatory tests and thight control of level of consciousness will be performed. In the intervention group four units of cryopreciptate 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

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Iran (Islamic Republic of)

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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 cryopericiptate and conventional treatment on prevention of brain contusion expansion in trauma patients

Public title
Effect of cryopercipitate 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 cryopercipitate 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 receivig conservative routine care; intravenous adminestration 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 grouo 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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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

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Position

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Latest degree

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Person responsible for updating data

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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 limitted number of people; but its results can be cited in meta_ analyze.
From where data/document is obtainable
Dr. Mohammd 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