Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of treatment of chronic subdural hemorrhage by siphon method in patients referred to Bahonar Hospital in Kerman

Protocol summary

Study aim

The aim of this study is to compare the possible advantages and disadvantages of siphon washing method with traditional method in chronic subdural hemorrhage(CSDH) .

Design

Clinical trial with 2 groups, with parallel groups (, double-blind, randomized, phase 0 on 60 patients. Using random numbers

Settings and conduct

The operating room of Bahonar Hospital in Kerman will have two surgical procedures. Due to the patient being unconscious, one side will be blind . The type of surgery is performed by a neurosurgeon, and therefore the physician evaluating the consequences of the surgery and analyzing the data will be unaware of the treatment protocol.

Participants/Inclusion and exclusion criteria

Patients with CSDH confirmed by CT scan for more than 72hr with GCS decline, neurological deficit and gait disorder should be referred to Bahonar Hospital

Intervention groups

Siphon group : first the burr hole is placed and then after opening the Dura by placing the catheter in the part of the hematoma that is the largest and lower volume, continuously by pouring saline into the burr hole from the catheter. The distal head is located below the patient's head. The chronic hematoma is continuously drained until clear fluid comes out. Finally, after ventilating and fixing the catheter, the skin is closed and a drain is placed at the level of the head. burr hole method: In each patient a 16 mm diameter burr hole is created in the convexity of the skull under general anesthesia. The dura and outer membrane are incised and the hematoma cavity is flushed with warm physiological saline until clear fluid is removed and the space is filled with isotonic saline, then the drain is placed in the empty space.

Main outcome variables

Recurrence CSDH

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211130053232N1**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **prospective**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Mohammad Agha Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3223 5011

Email address

drmohammadi24@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of treatment of chronic subdural hemorrhage by siphon method in patients referred to Bahonar Hospital in Kerman

Public title
Evaluation of treatment of chronic cerebral hemorrhage by siphon method in patients referred to Bahonar Hospital in Kerman

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Chronic subdural hemorrhage for more than 72 hours Decrease GCS Neurological deficits Gait disorder

Exclusion criteria:
Patient dissatisfaction in participating in the study Taking anticoagulants History of craniocerebral surgery Rebleeding after burr hole craniostomy

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, sampling is first available and then eligible patients will be randomly assigned to two groups. For this purpose, first a random sequence will be created from the table of random numbers. Then the extracted even numbers will be assigned to the siphon group and the odd numbers will be assigned to the burr hole group. This process will continue to reach the sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding is two-way blind so that the participant and the physician evaluating the outcome and the data analyzer are unaware of the type of surgical procedure And only the surgeon will know the type of operation

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Kerman,The beginning of Haft Bagh Alavi Road, Kerman University of Medical Sciences Campus

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2021-11-23, 1400/09/02

Ethics committee reference number
IR.KMU.REC.1400.496

Health conditions studied

1

Description of health condition studied
Subdural hemorrhage

ICD-10 code
I62.03

ICD-10 code description
Nontraumatic chronic subdural hemorrhage

Primary outcomes

1

Description
Treatment of chronic subdural hemorrhage by siphon method

Timepoint
12 months

Method of measurement
Checklist and examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Siphon craniostomy, first the burr hole is placed and then after opening the Dura by placing the catheter in the part of the hematoma that is the largest and lower volume, continuously by pouring saline into the burr hole from the catheter. The distal head is located below the patient's head. The chronic hematoma is continuously drained until clear fluid comes out. Finally, after ventilating and fixing the catheter, the skin

is closed and a drain is placed at the level of the head. burr hole method: In each patient a 16 mm diameter burr hole is created in the convexity of the skull under general anesthesia. The dura and outer membrane are incised and the hematoma cavity is flushed with warm physiological saline until clear fluid is removed and the space is filled with isotonic saline, then the drain is placed in the empty space.

Category

Treatment - Surgery

2

Description

Control group: burr hole craniostomy, In each patient a burr hole is created in the skull. The dura and outer membrane are incised and the hematoma cavity is washed with physiological saline until clear fluid is removed, and the space is filled with isotonic saline, then the drain is placed in the empty space.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Hospital in Kerman

Full name of responsible person

Mohammad Agha Mohammadi

Street address

Gharani

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7613747181

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drmohammadi24@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Somayeh crossroad

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Province

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7619813159

Phone

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kmu_research@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mohammad Agha Mohammadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Hamed Reyhani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery
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Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mohammad Agha Mohammadi
Position
Resident
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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
At the end of the study, some of the information, including side effects, the consequences of the surgical procedure after unrecognizing individuals, will be shared with health care professionals.
When the data will become available and for how long
2 months after data analysis
To whom data/document is available
Health researchers
Under which criteria data/document could be used
In order to use the results and during the written request
From where data/document is obtainable
Mohammad Agha Mohammadi- Email
What processes are involved for a request to access data/document
The purpose of accessing data - requesting e-mail- Information will be sent a week after the request
Comments