Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of neuroendoscopic and non-endoscopic surgical techniques in treatment of septated chronic subdural hematoma

Protocol summary

Study aim

Comparison of neuroendoscopic and non-endoscopic surgical techniques in treatment of septated chronic subdural hematoma

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. A simple blocking method will be used for randomization.

Settings and conduct

This study is performed in Besat Hospital of Hamadan, Hamadan Province. Sixty patients are randomly divided into two groups of endoscopic surgery and Barhol. Then, the mean duration of the operation, the recurrence rate 6 months after the clearance of mortality and postoperative morbidity, as well as the duration of hospitalization in patients will be evaluated.

Participants/Inclusion and exclusion criteria

Our study population is patients referred to Besat Educational and Medical Center in Hamedan in 1401. Inclusion criteria include: 1- Patients with chronic subdural hematoma 2- Patients with mixed density CT and 3- Satisfaction of patients or companions to enter the study Exclusion criteria include: 1- Patients with low level of consciousness (Glasgow coma score less than 9) 2- Acute subdural hematoma 3- Patients with involvement of several organs 4- Patients with a history of liver cirrhosis and coagulation disorders 5- Patients with a history Shant

Intervention groups

Intervention group 1: Patients who undergo endoscopic surgery. Control group: Patients who undergo surgery to perform surgery in the Brahol method (single or double Brahol).

Main outcome variables

Duration of surgery Mortality Morbidity Recurrence after 6 months Duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N14**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **prospective**

Last update: **2022-02-19, 1400/11/30**
Update count: **0**

Registration date

2022-02-19, 1400/11/30

Registrant information

Name

Zabihullah Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3232 3232

Email address

oabstudent@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-20, 1400/12/29

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of neuroendoscopic and non-endoscopic surgical techniques in treatment of septated chronic subdural hematoma

Public title
Comparison of neuroendoscopic and non-endoscopic surgical techniques in treatment of septated chronic subdural hematoma

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with chronic subdural hematoma Patients with CT with Mixed Density Patient consent or patient companion to enter the study

Exclusion criteria:
Patients with low level of consciousness (GCS less than 9) Acute subdural hematoma Patients with multi organ damage Patients with a history of liver cirrhosis Patients with a history of shunt

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants in the study were randomly divided into two groups using simple blocking method: 1) endoscopic surgery intervention (A) or 2) control, naked (single or double bare) surgery (B). They will be. In this way, various quadrilateral blocks are first created using a sealed envelope (AABB, BBAA, ABAB, BABA, ABBA and BABA). One of these blocks is selected randomly and according to the order mentioned in the selected block, patients will be divided into one of two groups A or B. Then randomization is performed for other patients in the same way.

Blinding (investigator's opinion)
Double blinded

Blinding description
Outcome Assessor: The study facilitator (hands in the field of neurosurgery) will assess the outcome during surgery, hospitalization and 6 months after discharge without knowing the patients in the surgery group. Patients participating in the study are not aware of being in the surgical group due to anesthesia and unfamiliarity with surgical methods. Analyzer: The data analyst is also unaware of the inclusion of individuals in the study and analyzes the data using defined codes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Central Organization of Hamadan University of Medical Sciences.Shahid Fahmideh Street. Research Square. Hamadan. Hamadan Province

City
Hamadan

Province
Hamadan

Postal code
6517838736

Approval date
2021-12-10, 1400/09/19

Ethics committee reference number
IR.HMSHA.REC.1400.717

Health conditions studied

1

Description of health condition studied
Subdural hematoma

ICD-10 code
S06.5

ICD-10 code description
Traumatic subdural hemorrhage

Primary outcomes

1

Description
Duration of surgery

Timepoint
During surgery in the operating room

Method of measurement
Using field observation and survey

2

Description
Recurrence rate of surgery

Timepoint
6 months after discharge

Method of measurement
By examining and performing the relevant tests

3

Description
mortality rate
Timepoint
After surgery
Method of measurement
Check mortality statistics

4

Description
Morbidity
Timepoint
After surgery
Method of measurement
Question from the patient

5

Description
Duration of hospitalization
Timepoint
After surgery
Method of measurement
Check the patient file

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients who undergo endoscopic surgery.
Category
Treatment - Surgery

2

Description
Control group: Patients who undergo surgery to perform surgery in the Brahol method (single or double Brahol).
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital, Hamedan
Full name of responsible person
Fahimeh Esmaeeli
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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استان همدان، همدان، میدان پژوهش، خیابان شهید فهمیده، ستاد دانشگاه علوم پزشکی همدان
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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
Hamedan 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
Birjand University of Medical Sciences
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Zabihullah Mohaghegh
Position
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available