

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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 Brahoh method (single or double Brahoh).

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		Other design features	
Public title	Comparison of neuroendoscopic and non-endoscopic surgical techniques in treatment of septated chronic subdural hematoma	Secondary Ids	empty
Purpose	Treatment	Ethics committees	
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	<u>1</u>	
Age	No age limit	Ethics committee	
Gender	Both	Name of ethics committee	Ethics Committee of Hamadan University of Medical Sciences
Phase	3	Street address	Central Organization of Hamadan University of Medical Sciences.Shahid Fahmideh Street. Research Square. Hamadan. Hamadan Province
Groups that have been masked	- Participant - Outcome assessor	City	Hamadan
Sample size	Target sample size: 30	Province	Hamadan
Randomization (investigator's opinion)	Randomized	Postal code	6517838736
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.	Approval date	2021-12-10, 1400/09/19
Blinding (investigator's opinion)	Double blinded	Ethics committee reference number	IR.HMSHA.REC.1400.717
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.	Health conditions studied	
Placebo	Not used	<u>1</u>	
Assignment	Parallel	Description of health condition studied	Subdural hematoma
		ICD-10 code	S06.5
		ICD-10 code description	Traumatic subdural hemorrhage
		Primary outcomes	
		<u>1</u>	
		Description	Duration of surgery
		Timepoint	During surgery in the operating room
		Method of measurement	Using field observation and survey
		<u>2</u>	
		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

Street address

Besat Hospital. Shahid Beheshti Blvd. Hamedan,

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Fahimeh Esmaeeli

Street address

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

Full name of responsible person

Zabihullah Mohaghegh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Full name of responsible person

Zabihullah Mohaghegh

Position

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Latest degree

Bachelor

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