

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation and comparison of the results of acute subdural hematoma evacuation by two methods of multidural stabs versus open dural flap

Protocol summary

Study aim

Comparison of the results of acute cerebral subdural hematoma drainage using two methods: multidural slit and duraplasty.

Design

A controlled, double-blind, randomized, phase 3 clinical trial with parallel groups on 94 patients. The randomization will be performed using a block method using software called Sealed Envelope.

Settings and conduct

This study will be conducted on 94 patients with subdural hematoma who are candidates for surgery at Vali Asr Hospital in Arak. This study will be conducted in a double-blind manner and patients, clinical caregivers, and outcome assessors will be blinded to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 60 years, acute subdural hematoma requiring surgery without other associated bleeding. Exclusion criteria: underlying coagulation disorder, brain tumor

Intervention groups

Intervention group 1: 47 patients will undergo surgery using the Durmerflap technique, in which a decompression craniectomy is performed by removing parts of the frontal, temporal, parietal, and occipital bones, resulting in a large bone flap (diameter > 12 cm). The dura is then opened in a C-shape towards the base of the skull to drain the hematoma and hemostasis is achieved. (Complete duraplasty is performed with the temporalis or pericranium fascia). Intervention group 2: 47 patients will undergo surgery using the multidural slit technique. This is a decompression procedure for acute subdural hematoma in the presence of severe cerebral edema and midline shift to preserve the arachnoid tissue, pia, brain tissue, and its vessels by opening the dura. Normal saline is continuously used to flush the dura of blood and clots, and a soft silastic catheter is inserted to remove clots stuck to the surface of the

brain.

Main outcome variables

Assessment of level of consciousness, Glasgow Outcome Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251228068472N1**

Registration date: **2026-02-14, 1404/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2026-02-14, 1404/11/25**

Update count: **0**

Registration date

2026-02-14, 1404/11/25

Registrant information

Name

Samar Kamalifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-02-14, 1404/11/25

Expected recruitment end date

2026-04-19, 1405/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the results of acute subdural hematoma evacuation by two methods of multidural stabs versus open dural flap

Public title

Comparison of multidural slit and dural flap in the evacuation of acute subdural hematoma of the brain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 60 years Patients with acute subdural hematoma requiring surgery without other associated bleeding

Exclusion criteria:

Underlying coagulation disorder Brain tumor

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate the samples, a block randomization method with blocks of 8 will be used. Thus, using the block random number generation software, a randomization sequence will be generated in proportion to the required sample size for the two groups. Initially, all the cases in which the 2 letters A, B can be arranged together in a block of 8 are generated. Then, a block is randomly selected from the blocks by placing them, and the arrangement pattern in that block will be used to allocate the participants. Then, this block is placed in the main container and another block will be selected again. All of this will be done with a software called Sealed Envelope. Using this method, concealment will also be observed. The concept of concealment is to make the allocation of individuals to groups unpredictable. In fact, the researcher will not be able to predict which group the next person will be placed in.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double-blind, for this purpose, patients and outcome assessors are blinded. Patients who are unaware of the type of surgery due to reduced level of consciousness and the type of technique performed will

be unaware of the surgery. On the other hand, the surgery will be performed by a neurosurgeon and the follow-up and evaluation of patients will be performed by the intern responsible for the project. Therefore, the outcome assessor, who is the intern responsible for the project, will be unaware of the patient grouping and will evaluate patients based on the case number and information received from the attending (neurosurgeon).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Payambar Azam Complex, Sardasht Town

City

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Province

Markazi

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3848176341

Approval date

2024-05-19, 1403/02/30

Ethics committee reference number

IR.ARAKMU.REC.1403.076

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**

Level of consciousness

Timepoint

Before and after the intervention

Method of measurement

Glasgow Coma Scale

2

Description

Disease outcome based on Glasgow Outcome Scale

Timepoint

Before and after the intervention

Method of measurement

Glasgow Outcome Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 94 patients with subdural hematoma will undergo surgery using the Durmer flap technique. In this method, a decompression craniectomy is performed by removing parts of the frontal, temporal, parietal, and occipital bones, resulting in the creation of a large bone flap (diameter > 12 cm). The dura is then opened in a C-shape towards the base of the skull to drain the hematoma and achieve hemostasis. (Complete duraplasty is performed with the temporalis fascia or pericranium). The advantage of this method is that it immediately reduces intracranial pressure.

Category

Treatment - Surgery

2

Description

Intervention group: Intervention group 2: 94 patients with subdural hematoma will undergo surgery using the multidural slit technique. This is a decompression procedure for acute subdural hematoma in the presence of severe cerebral edema and midline shift to preserve the arachnoid tissue, pia, brain tissue, and its vessels by opening the dura. In this surgical procedure, several linear incisions of 5-8 mm in length are made with a No. 11 knife, in horizontal lines, parallel to the vessels, and 2-2.5 cm apart. Caution is that the tip of the knife should not penetrate more than 0.5 to 1.0 mm in depth. Normal saline is continuously used to flush the dura from blood and clots, and a soft silastic catheter is inserted to remove clots stuck on the brain surface.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Samar Kamalifar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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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