Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
Arak
Province
Markazi
Postal code
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
Samar kamalifar
Street address
Payambar Azam Complex, Sardasht Town
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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