

# 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)

##### Phone

+98 86 3417 3505

##### Email address

samarkamalifar@gmail.com

##### 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

#### City

Arak

#### Province

Markazi

#### Postal code

3814957558

#### Phone

+98 86 6565 0000

#### Email

info@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Behzad Khansarinejad

##### Street address

Payambar Azam Complex, Sardasht Town

##### City

Arak

##### Province

Markazi

##### Postal code

3848176341

##### Phone

+98 86 3417 3532

##### Email

behzad.khansarinejad@arakmu.ac.ir

#### 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

**Street address**

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**Person responsible for scientific 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**

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**Person responsible for updating data****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**

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**Fax****Email**

samarkamalifar@gmail.com

**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