

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 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

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

##### Design

The study is a randomized, community-based, and pragmatic clinical trial consisting of 60 patients in 2 parallel groups with double-blind design

##### Settings and conduct

This study will be carried out at Tabriz Imam Hospital in a two-blind manner,

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) patients aged 18 to 60 years 2) patients with Glasgow outcome score (GCS) lower or equal to 13 3) Patients with Acute subdural hematomas  
Exit criteria: 1) Patient dissatisfaction 2). disorder such as brain aneurysm 3).existence of an bleeding disorder

##### Intervention groups

Intervention group Multi-Dural Stabs. parallel to the slippery vein of the vein 4-5 mm and 2-2.5 cm spacing between the hematoma lines will be evacuated.  
Intervention group dural flap .flap surgery, expanded hemoptysis, and then duraplasty

##### Main outcome variables

Glasgow coma scale, Glasgow Outcome Scale, mortality rate, Brain herniation, Surgical site infection

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120527009878N12**  
Registration date: **2020-01-20, 1398/10/30**  
Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-20, 1398/10/30**

Update count: **0**

##### Registration date

2020-01-20, 1398/10/30

##### Registrant information

###### Name

Firooz Salehpour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3334 0830

###### Email address

salehpourf@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-22, 1398/04/01

##### Expected recruitment end date

2021-03-20, 1399/12/30

##### 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

Evaluation two methods of multidural stabs and open dural flap on acute subdural hematoma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

patients aged 18 to 60 years patients with Glasgow

outcome score (GCS) lower or equal to 13 Patients with Acute subdural hematomas

**Exclusion criteria:**

Patient dissatisfaction disorder such as brain aneurysm existence of an bleeding disorder

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided into two groups by last digit of the patient's file number . Even number for group open-dural flap and odd number for multi-dural stabs

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

After selecting study groups based on last digit of the patient's file number. 1 and 2 labels were assigned to the target group by the secretary. Then, the patients will be intervened by the researcher in the operating room in the case group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tabriz Medical School

**Street address**

Floor 3, Center building N 2, Tabriz university of medical sciences, Golgasht street.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

04133357310

**Approval date**

2019-12-23, 1398/10/02

**Ethics committee reference number**

IR.TBZMED.REC.1398.1049

**Health conditions studied**

**1**

**Description of health condition studied**

Traumatic subdural haemorrhage

**ICD-10 code**

S06.5X

**ICD-10 code description**

Traumatic subdural hemorrhage

**Primary outcomes**

**1**

**Description**

Disability Rating Scale (DRS) scoring

**Timepoint**

daily until discharge

**Method of measurement**

Disability Rating Scale questionnaire

**2**

**Description**

Glasgow Outcome Scale

**Timepoint**

daily until discharge

**Method of measurement**

Glasgow Outcome Scale questionnaire

**Secondary outcomes**

**1**

**Description**

Brain herniation

**Timepoint**

During 6 months after surgery

**Method of measurement**

Recurrent signs and symptoms of the patient and radiologic evidences on MRI

**2**

**Description**

Surgical site infection

**Timepoint**

2 days, 2 weeks, 3 months and 6 months after intervention

**Method of measurement**

physical examination, ESR and CRP lab tests

**3**

**Description**

mortality rate

**Timepoint**

In duration 6 weeks after traumatic brain injury

**Method of measurement**

Questionnaire on complications after traumatic brain injury

## Intervention groups

### 1

#### Description

Intervention group1: Multi-Dural Stabs. parallel to the slippery vein of the vein 4-5 mm and 2-2.5 cm spacing between the hematoma lines will be evacuated.

#### Category

Treatment - Surgery

### 2

#### Description

Intervention group: dural flap .flap surgery, expanded hemoptysis, and then duraplasty

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Neurosurgery Ward of Emem Reza hospital

##### Full name of responsible person

Hossein Hamadani

##### Street address

Azadi St. Golghast St.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

##### Phone

+98 41 3334 7054

##### Email

hosseinhamadani@gmail.com

##### Web page address

<https://imamreza.tbzmed.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Ali Meshkini

##### Street address

Azadi St., Golghast Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

##### Phone

+98 41 3336 3176

#### Email

Meshkinia@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Moslem Shakeri

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Neurosurgery

##### Street address

Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614756

##### Phone

+98 41 3334 7054

##### Email

shakerim@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Moslem Shakeri

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

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shakerim@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hossein Hamadani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

**Street address**

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**Email**

hosseinhamadani@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

A portion of the data that represents the final outcome

**When the data will become available and for how long**

A portion of the data that represents the final outcome

**To whom data/document is available**

Neuropsychiatric specialists in coordination with the presenter

**Under which criteria data/document could be used**

The use of data to improve patients' treatment processes is safe

**From where data/document is obtainable**

Person responsible for updating study information

**What processes are involved for a request to access data/document**

Requesting data and study documents will be done by correspondence with the person responsible for updating the study information

**Comments**