Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 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
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

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Iran (Islamic Republic of)

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+98 41 3334 0830

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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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ali Meshkini
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Azadi St., Golghast Street
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5166614756
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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
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Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street, Tabriz
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Person responsible for updating data

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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