Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing Dural closure with watertight suturing and Approximate of Dura in supratentorial craniotomy: A single blined randomized controlled clinical trial

Protocol summary

Study aim

The aim of this study is to compare the efficacy and safety of two dural repair techniques (watertight closure and dural edge approximation) in patients undergoing supratentorial craniotomy, in terms of postoperative complications, ease of performance, and operative time.

Design

A phase II, randomized, single-blind, parallel-group, controlled clinical trial involving 90 patients was conducted. Randomization was performed using the Sealed Envelope online randomization service (www.sealedenvelope.com).

Settings and conduct

This single-blind, randomized controlled clinical trial will involve 90 patients undergoing supratentorial craniotomy at Ayatollah Rouhani Hospital, Babol, Iran. Patients will be randomly assigned to two parallel groups: watertight dural closure (intervention group) and dural edge approximation (control group). Patients will be blinded to the dural repair technique used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients who were candidates for supratentorial craniotomy during this period due to brain tumors, subdural hematomas, epidural hematomas, or intracerebral hemorrhages and age range 18 to 70 years
Exclusion criteria: History of prior brain surgery, Patients who simultaneously require another emergency surgical procedure, Posterior fossa craniotomy, Requirement for a bilateral craniotomy, Presence of a prior infection at the surgical site.

Intervention groups

For one group, the torn dura is repaired using the watertight method, and for the other group, it is repaired using the by approximating the dural edges method.

Main outcome variables

Total operative time measured in minutes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261119071840N1**
Registration date: **2026-11-22, 1405/09/01**
Registration timing: **prospective**

Last update: **2026-11-22, 1405/09/01**
Update count: **0**

Registration date

2026-11-22, 1405/09/01

Registrant information

Name

Ebrahim Hejazian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 9592

Email address

sehbb1404@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-12-22, 1405/10/01

Expected recruitment end date

2027-05-22, 1406/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing Dural closure with watertight suturing and Approximate of Dura in supratentorial craniotomy: A single blined randomized controlled clinical trial

Public title
Comparing Dural closure with watertight suturing and Approximate of Dura in supratentorial craniotomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients who were candidates for supratentorial craniotomy during this period due to brain tumors, subdural hematomas, epidural hematomas, or intracerebral hemorrhages. Age range 18 to 70 years

Exclusion criteria:
History of prior brain surgery Patients who simultaneously require another emergency surgical procedure Posterior fossa craniotomy Requirement for a bilateral craniotomy Presence of a prior infection at the surgical site

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using the permuted block randomization method, with randomly varying block sizes of 4 and 2 and an allocation ratio of 1:1. Accordingly, an equal number of participants will be assigned to each intervention group within each block. The randomization sequence will be generated by a statistician using the online software available at www.sealedenvelope.com

Blinding (investigator's opinion)
Single blinded

Blinding description
Since patients undergo surgery under general anesthesia, they will be unaware of the duraplasty technique used. Therefore, the study will be conducted as a single-blind trial.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Health Research Institute- Babol University of Medical Sciences

Street address
Ganj-Afrouz Street,

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۴۵

Approval date
2026-09-20, 1405/06/29

Ethics committee reference number
IR.MUBABOL.HRI.REC.1405.238

Health conditions studied

1

Description of health condition studied
Spinal Dural Injury

ICD-10 code
A17.81

ICD-10 code description
Tuberculoma of brain and spinal cord

Primary outcomes

1

Description
Total operative time measured in minutes.

Timepoint
During the surgery and immediately after the completion of the surgery

Method of measurement
Time recorded in the checklist

Secondary outcomes

1

Description
Infection

Timepoint
Immediately following the duraplasty surgery up to the two-month follow-up.

Method of measurement
Laboratory results and culture of secretions

2

Description
Cerebrospinal fluid (CSF)

Timepoint

Immediately after duraplasty surgery up to the two-month follow-up.

Method of measurement

The function of the drain to check the leak of cerebrospinal fluid (CSF)

Intervention groups

1

Description

Intervention group: Incision of the scalp, removal of the skull bone, opening of the dura, evacuation of the hematoma or tumor, watertight closure of the dura, placement of a drain, and suturing of the subcutaneous tissue and scal.

Category

Treatment - Surgery

2

Description

Control group: Incising the scalp, removing a portion of the skull, opening the dura, evacuating the hematoma or tumor, suturing the dura by approximating its edges, placing a drain, and suturing the subcutaneous tissue and scalp.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital, Babol

Full name of responsible person

Dr. Seyed Ebrahim Hejazian

Street address

Ayatollah Rouhani Hospital, Ganj-Afrooz Street, Daneshgah Square, Babol

City

Babol

Province

Mazandaran

Postal code

4717641367

Phone

+98 11 3223 8302

Email

sehbb1404@gmail.com

Web page address

https://www.drsaina.com/hospital

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr.Reza Ghadimi

Street address

Vice-Chancellery for Research and Technology, Babol University of Medical Sciences, Babol, Ganj-Afrouz Street, Mazandaran

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶۴۷۷۵۴

Phone

+98 11 3219 7667

Email

research@mubabol.ac.ir

Web page address

https://research.mubabol.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr. Mehdi Habibitabar

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Babol University of Medical Sciences, Ganj-Afrouz Street, Babol, Mazandaran

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶۴۷۷۴۵

Phone

+98 11 3219 9592

Email

dr.habibitabar62@gmail.com

Web page address

https://www.mubabol.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Seyed Ebrahim Hejazian

Position

Asistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurosurgery

Street address

Babol University of Medical Sciences, Ganj-Afrouz Street, Babol, Mazandaran

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶۴۷۷۴۵

Phone

+98 11 3219 9592

Email

sehbb1404@gmail.com

Web page address

https://www.mubabol.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Seyed Ebrahim Hejazian

Position

Asistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurosurgery

Street address

Mazandaran, Babol, Ganj-Afrouz Street, Babol University of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶۴۷۷۴۵

Phone

+98 11 3219 9592

Email

sehbb1404@gmail.com

Web page address

https://www.mubabol.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

-

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available