

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### comparisone of 5day, 3month, 6month and 1year prognosis of treatment of patient with malignant intracranial hypertension by decompressive craniotomy and hinge cranioplasty in Sina hospital in 2016-2017

#### Protocol summary

##### Study aim

comparison of outcome and complication of hinge cranioplasty and decompressive craniectomy in treatment of malignant intracranial hypertension and replacing this method of surgery (hinge cranioplasty) in treatment of malignant intracranial hypertension if outcome is better and complication is less.

##### Design

Randomized parallel group trial with blinded outcome assessment. randomization was done with sealed envelop method and composed 14 patient underwent hinge cranioplasty and 14 underwent decompressive craniectomy.

##### Settings and conduct

surgery is done on neurosurgery operation room of Sina hospital with blindness of surgeon about type cranioplasty or craniectomy and ICU care and management by blindness of nurse.

##### Participants/Inclusion and exclusion criteria

patient who underwent cerebral decompression:  
1.patient with diagnosis of ischemic cerebrovascular accident and intracranial hypertension above 20cmHg despite maximum medical therapy or sign of brain herniation or decrease level of consciousnesses or focal neurological deficit. 2.patient with intracerebral hematoma above 30 cc and 5mm midline shift and decrease level of consciousness and focal neurological deficit 3.patient with traumatic subdural hematoma or intracerebral hematoma need operation for hematoma evacuation.

##### Intervention groups

patient with diagnosis of malignant intracranial hypertension due to internal carotid territory infarction , traumatic and non traumatic intracranial hematoma , subdural hematoma underwent cerebral decompression with one these two method: decompressive craniotomy or hinge cranioplasty

#### Main outcome variables

Intracranial pressure Glasgow outcome scale Modified rankin scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180515039678N1**

Registration date: **2018-11-21, 1397/08/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-11-21, 1397/08/30**

Update count: **0**

##### Registration date

2018-11-21, 1397/08/30

##### Registrant information

##### Name

Mohammad mostafa Harifi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3556 4455

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-15, 1396/10/25

##### Expected recruitment end date

2020-01-15, 1398/10/25

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

comparisons of 5day, 3month, 6month and 1year prognosis of treatment of patient with malignant intracranial hypertension by decompressive craniotomy and hinge cranioplasty in Sina hospital in 2016-2017

**Public title**

hinge cranioplasty in treatment of malignant intracranial hypertension

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patient with diagnosis of malignant intracranial hypertension indicate cerebral decompression despite medical management hemorrhagic and ischemic infarct of internal carotid territory patient with diagnosis of unilateral internal carotid territory intracranial hematoma that indicate surgery without coincidence hematoma E.g Subdural hematoma patient with traumatic unilateral temporal, parietal, frontal subdural hematoma or combination of them in one side even with same side contusion(not need evacuation) with intracranial pressure above 20cmHg or protrusion of brain parenchyma out of site of craniectomy

**Exclusion criteria:**

pregnant women patient died during first day after operation occipital or cerebellar infarction (non internal carotid territory) patient with history of psychosis concomitant lesion e.g Brain tumor concomitant cerebrovascular lesion e.g aneurysm patient without follow up patient with history of neurological disorder that cause neurological deficit multiple cerebrovascular accident or multiple hemorrhagic lesion history of previous cerebrovascular accident bilateral cerebrovascular accident or bilateral hemorrhage concomitant subdural hematoma and intracranial hemorrhage traumatic posterior fossa hematoma intraventricular hemorrhage patient with subdural hematoma and glasgow coma scale 3 without brain palpation depressed fracture and patient with dis-usable bone flap patient who underwent temporal lobectomy traumatic injury to thoracic, abdomen, pelvic and their content that need intervention

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **28**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

patient who indicate cerebral decompression (as mentioned before) with sealed envelope method and announce the surgeon who is blind at the end of surgery the method of surgery termination(Hinge cranioplasty or decompressive craniectomy). patient post operation underwent ICU care under supervision of director of study and nursing who are blind of type of surgery.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary IDs**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Imam Khomeini St Hasan abad Sq SINA hospital

**City**

Tehran

**Province**

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**Postal code**

1136746911

**Approval date**

2018-01-15, 1396/10/25

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1396.4230

**Health conditions studied****1****Description of health condition studied**

patient with malignant intracranial hypertension

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

short term and long term evaluation of effect of hinge cranioplasty in decreasing intracranial pressure

**Timepoint**

5 day - 3 month - 6 month - 1year

**Method of measurement**

ICP monitoring with subdural catheter in first 5 day - evaluating the patient with Modified Rankin scale and Glasgow Outcome scale in 3 and 6 month and 1year

**Secondary outcomes****1****Description**

long term quality of life and complication

**Timepoint**

3 month - 6 month -1 year

**Method of measurement**

Modified Rankin scale and Glasgow Outcome scale

**Intervention groups****1****Description**

Intervention group: patient who had malignant intracranial hypertension and not relieved with medical management randomly divided to two groups. On hinge cranioplasty patient underwent question mark incision and after dissection of skin flap the pericranium will be dissected and used for duraplasty after the removal of the frontotemporoparietal bone flap. After duraplasty bone flap will be attached loosely with one miniplate to frontal bone and the temporal and parietal miniplate just attached to the bone flap.

**Category**

N/A

**2****Description**

Control group: On decompressive craniectomy patient underwent question mark incision and after dissection of skin flap the pericranium will be dissected and used for duraplasty after the removal of the frontotemporoparietal bone flap and it will be inserted on the upper quadrant of the abdomen on the same side of craniectomy. patient underwent cranioplasty after 6 months.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina hospital

**Full name of responsible person**

Mohammad Mostafa Harifi

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

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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**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Mostafa Harifi

**Position**

Resident of neurosurgery

**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
Seyed Abolghasem Mortazavi  
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Associate Professor of neurosurgery  
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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

Yes - There is 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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

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

all data can be published after disguised the patient

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

2 Month after publishing the result

### To whom data/document is available

data is available for researcher , physician , therapeutic and educational and scientific center

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

for increasing treatment efficacy

### From where data/document is obtainable

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00989168289382 Tehran hasan abad Sq emam khomeini st sina hospital

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

contacing with authors

### Comments