

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Name of organization / entity

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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

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Imam Khomeini St Hasan abad Sq SINA hospital

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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

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

contacing with authors

Comments