

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of one burr hole vs two burr holes surgery in recurrence of chronic subdural hematoma

Protocol summary

Study aim

to compare to method of surgery (one bur hole vs two bur hole) in chronic subdural hematoma treatment

Design

as frequent retrospective studies in this matter, no difference between these two methods has been told, so we decide to design a prospective interventional study. randomization will be done by the 4, 6, and 8 block methods. then concealment will be done so the person who does this randomization, does not become aware of group interventions.

Settings and conduct

patients who come to Shariati hospital and meet inclusion/exclusion criteria will be randomized in one of two methods of surgery after receiving informed consent. as it is not possible to blind the caregivers, people who collect and analyze data will be blind to intervention groups.

Participants/Inclusion and exclusion criteria

men and women patients more than 18 years old that cSDH diagnosed with a brain CT scan and has a 5 mm or more midline shift and/or obvious pressure effect on the underlying cortex and/or clinical symptoms justified by hematoma will be included. patients with less than 18 years of age, pregnancy, breastfeeding, acute sepsis, history of brain shunt due to hydrocephaly, active psychological disease, patients who can not participate in follow-up, and uncorrectable coagulopathy before surgery will be excluded.

Intervention groups

patients will randomly be put in one or two bur hole intervention groups. finally, recurrence will be evaluated in these two groups.

Main outcome variables

recurrence is the main outcome will be evaluate after follow up period.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221016056192N1**

Registration date: **2022-10-27, 1401/08/05**

Registration timing: **prospective**

Last update: **2022-10-27, 1401/08/05**

Update count: **0**

Registration date

2022-10-27, 1401/08/05

Registrant information

Name

faramarz roohollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of one burr hole vs two burr holes surgery in recurrence of chronic subdural hematoma Public title A comparison of one burr hole vs two burr holes surgery in recurrence of chronic subdural hematoma Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: male or female patients more than 18 years old a minimum of 5 mm shift in brain CT scan obvious pressure effect on cortex underlying hematoma clinical symptoms justifiable to hematoma Exclusion criteria: pregnancy period breastfeeding period Sepsis active psychological disorders second surgery in first 48 hours because of technical issues patients who will not attend for follow up history of CSF diversion surgery empyema Age From 18 years old Gender Both Phase N/A Groups that have been masked • Data analyser Sample size Target sample size: 40 Randomization (investigator's opinion) Randomized Randomization description Random lists of patient allocation will be based on random blocks of 4, 6 and 8. The allocation would be concealed by the randomizer and the person in charge of randomization wouldn't be aware of the treatment they groups would receive. We will generate these random blocks using www.sealedenvelope.com. (Sealed Envelope Ltd. 2022. Create a blocked randomisation list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lits) Blinding (investigator's opinion) Single blinded Blinding description In this study, we want to investigate two different surgical procedures and since the patients and their relatives will receive a complete description of possible interventions in this study, blinding the patients wouldn't be possible. The patients will have the same number of scalp incisions and scars as the number of burr holes used and that's why they can't be blinded. This is also true for outcome assessors as they can also become aware of allocated groups. Those who'll be performing the procedure would become aware of it and they can't be blinded too. So, in this study only those who analyze and manage the data can be and will be blinded to the allocation. Placebo Not used Assignment	Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee shariati hospital ethics committe,tehran university of medical scince Street address kargar shomali sreet City Tehran Province Tehran Postal code 1411713135 Approval date 2022-07-04, 1401/04/13 Ethics committee reference number IR.TUMS.MEDICINE.REC.1401.279 Health conditions studied 1 Description of health condition studied chronic subdural hematoma in brain ICD-10 code I62.03 ICD-10 code description Nontraumatic chronic subdural hemorrhage Primary outcomes 1 Description recurrence outcome explained as incidence new deficits or exacerbation of clinical condition of patient any time after 48 hours to 6 months of surgery which will confirm with new brain CT scan revealing new hematoma. Timepoint 1 month and 6 month since surgery Method of measurement patients must attend to clinic for check up after 1 month and 6 month of surgery.. if there was neurological deficit CT will be done and recurrence will be assesd. Secondary outcomes empty Intervention groups
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Description

Intervention group: patients who will undergo one bur hole method surgery. patients will go under general anesthesia in both groups. in the supine position, superior to the superior temporal line, an incision will make. after preparing the skull bone, one bur hole will prepare by the perforator. after coagulation and opening of the dura and exiting of SDH fluid, we will irrigate into the hole with warm 37-degree sterile normal saline serum with a syringe until the exiting fluid is clear. a subperiosteal drain will be fixed. the small incision will be sutured by a 2-0 nylon thread. the drain will be equal to the level of the patient's head.

Category

Treatment - Surgery

2

Description

Control group: patients who will undergone two bur hole method surgery. all the steps will be the same as intervention group but instead of one incision, two incision will made superior to superior temporal line and one bur hole in each will be prepared. irrigation will be done from both holes. in the end, similar to other group, one drain will be fix in anterior incision.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Faramarz Roohollahi

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Kargar Shomali Ave, Shariati Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

Faramarz Roohollahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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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

Data will contain age, sex, surgery method, time of recurs, blood loss, primary symptoms and brain CT features. whole data will be shared after identified process was done.

When the data will become available and for how long

data files will be available one month after publication.

To whom data/document is available

Data will be available for people working in academic institutes .

Under which criteria data/document could be used

data will be shared for whom doing studies about outcomes of cSDH surgery to improve or describe methods of surgery.

From where data/document is obtainable

all people working in academic institutes can contact E-mail address below : faramarzroohollahi@yahoo.com

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

after receiving E-mail for accessing file of data, we will respond in less than 48 hours.

Comments