

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effect of topical corticosteroids combined with surgery in patients with chronic subdural hematoma

#### Protocol summary

##### Study aim

The effect of topical corticosteroids combined with surgery in patients with chronic subdural hematoma

##### Design

Randomized clinical trial on 30 patients, without control group, phase 2

##### Settings and conduct

On the third day after the operation, after monitoring the drain discharge, the drain is removed and before removing the drain, 40 mg of methylprednisolone sodium succinate is injected through the drain into the hematoma drainage chamber and the drain is completely removed.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: patients with chronic subdural hematoma  
exclusion criteria: acute subdural hematoma, traumatic ICH, Epidural hematoma, Depress FX, Open lesions, CSF leak, Previous shunt

##### Intervention groups

All patients referred to Ahvaz medical university hospitals with chronic subdural hematoma

##### Main outcome variables

Change in headache symptoms, change in postoperative seizure symptoms, change in postoperative paresis symptoms

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200911048685N1**

Registration date: **2021-02-21, 1399/12/03**

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

Last update: **2021-02-21, 1399/12/03**

Update count: **0**

##### Registration date

2021-02-21, 1399/12/03

##### Registrant information

###### Name

Davood Mahmoudi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3372 8265

###### Email address

mahmoudi.d@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-23, 1398/07/01

##### Expected recruitment end date

2021-04-21, 1400/02/01

##### Actual recruitment start date

2019-09-23, 1398/07/01

##### Actual recruitment end date

2021-04-21, 1400/02/01

##### Trial completion date

2021-04-21, 1400/02/01

##### Scientific title

The effect of topical corticosteroids combined with surgery in patients with chronic subdural hematoma

##### Public title

corticosteroids in chronic subdural hematoma

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

chronic subdural hematoma

###### Exclusion criteria:

Acute subdural hematoma traumatic ICH Epidural hematoma depress fx Intracranial mass and lesions open

lesion CSF leak previous shunt

**Age**

No age limit

**Gender**

Both

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: **30**

Actual sample size reached: **15**

**Randomization (investigator's opinion)**

Not randomized

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Ahvaz jundishapur university of medical sciences

**Street address**

Golestan, jundishapur university of medical sciences

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715753

**Approval date**

2020-10-27, 1399/08/06

**Ethics committee reference number**

IR.AJUMS.HGOLESTAN.REC.1399.086

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

chronic SubDural hematoma

**ICD-10 code**

I62.03

**ICD-10 code description**

Nontraumatic chronic subdural hemorrhage

**Primary outcomes****1****Description**

Recurrence of chronic subdural hemorrhage

**Timepoint**

6 months

**Method of measurement**

Designed questionnaire

**Secondary outcomes**

empty

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

Intervention group: A cross-sectional study will be performed on patients who have referred to hospitals related to Ahvaz University of Medical Sciences during subdural hematoma during 1398. Accordingly, after presenting the plan in the form of a research proposal and approving it in the relevant committees, the researcher, after receiving a license from Ahvaz Jundishapur University of Medical Sciences and a letter of introduction from the Vice Chancellor for Research and Technology, sampled based on the study process. And inclusion and exclusion criteria, in such a way that the goals and process of the study were stated as needed for patients, patients or patients' companions are asked to read and sign the informed consent form for the study and then patients enter Are studied. Accordingly, patients requiring surgical evacuation of subdural chronic hematoma who met the inclusion and exclusion criteria after nude craniotomy on the hematoma and drainage and rinsing of the hematoma with Ringer's serum implant a drain in the nostril of the craniotomy and the patient after surgery. The surgery is transferred to the neurosurgery department and monitored. On the third day after the operation, after monitoring the discharge of the drain, the drain is pulled and before removing the drain, 40 mg of methylprednisolone succinate is injected through the drain into the hematoma drain chamber. And the drain is completely stretched.

**Category**

Treatment - Drugs

**2****Description**

Control group: Distilled water is used for this group

**Category**

Placebo

**Recruitment centers****1****Recruitment center**

**Name of recruitment center**

Golestan Hospital

**Full name of responsible person**

Hossein Safari

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Golestan st. unishapur Ahvaz university of medical sciences

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+98 61 3333 0074

**Email**

davood.mahmoudi68@gmail.com

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammade Badavi

**Street address**

Golestan sreet.jondishapour univercity medical of science

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**Grant name**

Ahvaz Univercity Of Medical Sience

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Vice Chancellor for Research, Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Hossein Safari

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

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**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

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**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**

There is no information

**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