

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)

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+98 61 3372 8265

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

Ahvaz University of Medical Sciences

Full name of responsible person

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

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Medical doctor

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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