

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparative efficacy of early and late term imitation of prophylactic enoxaparin in prevention of thrombotic event and prevalence of hemorrhagic complications in patients with chronic subdural hematoma treated with Burr-hole craniostomy approach

Protocol summary

Study aim

Comparative efficacy of early and late initiation of prophylactic enoxaparin in prevention of thrombotic event and prevalence of hemorrhagic complications in patients with chronic subdural hematoma treated with Burr-hole craniostomy approach

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment number of cases: two groups of 30 patients

Settings and conduct

This study was conducted in two medical centers in Al-Zahra and Kashani in Isfahan and the researcher and the patient are unaware of which group each patient is in. the patients are grouped into 24 or 72-hour interval from operation-to-enoxaparin administration. then enoxaparin will be administered, all patients will be followed up with brain CT scan and both lower legs color Doppler ultrasonography

Participants/Inclusion and exclusion criteria

All people who are diagnosed with Chronic subdural haematoma undergoing surgery and are eligible to enter the study are included in the study, and those who are contraindicated in receiving enoxaparin or who refuse to enter the study are excluded from the study group.

Intervention groups

the patients are grouped into early and late-initiation interval from operation-to-enoxaparin administration. then enoxaparin will be administered in 24-hour or 72-hour after operation, all patients will be followed up with brain CT scan and both lower legs color Doppler ultrasonography

Main outcome variables

Bleeding events (epidural and cerebral hematoma)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200207046400N1**

Registration date: **2020-06-13, 1399/03/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-13, 1399/03/24**

Update count: **0**

Registration date

2020-06-13, 1399/03/24

Registrant information

Name

arman sourani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3447 2636

Email address

armansourani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy of early and late term imitation of prophylactic enoxaparin in prevention of thrombotic event and prevalence of hemorrhagic complications in patients with chronic subdural hematoma treated with Burr-hole craniostomy approach

Public title

efficacy of early and late term imitation of prophylactic enoxaparin in prevention of thrombotic event and prevalence of hemorrhagic complications in patients with chronic subdural hematoma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who have been diagnosed with Chronic subdural haematoma who undergo surgical evacuation
Patient consent

Exclusion criteria:

contraindications to receive enoxaparin occurrence of existence of deep venous thrombus in the period of study existence of hematoma in post operative brain CT scan

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

the patients will be randomly allocated using statistical software. then they will be assigned into two major arms of study, early and late-enoxaparin administration.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, after explaining the goals to the patient, he is given informed consent. Patients are randomly divided into two groups, but neither group is aware of which group. The researcher does not know which group each patient belongs to. However, the clinical caregiver is aware of the group of patients and uses the drug in accordance with the group in which the patient is placed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Esfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۱

Approval date

2020-01-21, 1398/11/01

Ethics committee reference number

IR.MUI.MED.REC.1398.664

Health conditions studied

1

Description of health condition studied

Chronic subdural haematoma

ICD-10 code

I62. 03

ICD-10 code description

Chronic subdural haematoma

Primary outcomes

1

Description

Bleeding events (epidural and cerebral hematoma)

Timepoint

24 , 72 hours after surgery by craniotomy

Method of measurement

Brain CT scan

2

Description

Thrombotic events

Timepoint

24 , 72 hours after surgery by craniotomy

Method of measurement

Double-sided Doppler ultrasound of the lower extremities

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Enoxaparin with a prophylactic dose 24 hours per day at a dose of 1 mg / kg (maximum 40 mg)

Category

Treatment - Drugs

2

Description

Control group: Enoxaparin with a prophylactic dose 72 hours per day at a dose of 1 mg / kg (maximum 40 mg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Arman Sourani

Street address

Al-Zahra hospital, Sofeh St.,Isfahan,Iran

City

Esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

armansourani@gmail.com

2

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Arman Sourani

Street address

Kashani ST

City

Esfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3233 0091

Email

armansourani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjuye Javanmardi

Street address

Isfahan University of Medical Sciences, hezar jarib S.T

City

Esfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۱

Phone

+98 31 3668 0048

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

1

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

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Shafiei

Position

استادیار

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Esfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۱

Phone

+98 31 3668 0048

Email

Mehdishafiei82@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Shafiei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Esfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۱

Phone

+98 31 3668 0048

Email

Mehdishafiei82@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Shafiei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.,

City

Esfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۱

Phone

+98 31 3668 0048

Email

Mehdishafiei82@gmail.com

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

Not applicable

Title and more details about the data/document

Data can be shared after people become unrecognizable

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Just for study and new research people

From where data/document is obtainable

Email Author responsible: Mehdishafiei82@gmail.com

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

in first step, the request should be sent to corresponding author. the reasons, affiliations and authenticity of request will be investigated by author. then with concealing the personal data of patients due to privacy concerns and ethical issues, requested data will be available in following 2 weeks after appeal.

Comments