Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy Comparison of Unfractionated Heparin and Low Molecular Weight Heparin(LMWH) in Deep Vein Thrombosis Prophylaxis for Brain Tumor craniotomy

Protocol summary

Summary

Objectives: Craniotomy because of post operative immobility is a risk factor for venous thrombosis. The aim of the present study was to compare the effect of tow routine prophylactic treatment; unfractionated heparin and low-molecular-weight heparin (clexane) in preventing DVT in patients with Brain tumor undergoing elective craniotomy. Design and setting: 154 Patients candidate for elective craniotomy due to brain tumor were enrolled in this randomized, double – blinded, controlled clinical trial from 2009 to 2010 in Isfahan IRAN. Patients were divided two groups after craniotomy. Participant including major eligibility criteria: Patients candidate for elective craniotomy due to brain tumor were enrolled in this study. Exclusion criteria: Patients with bleeding into the primary lesion; history of thrombotic events in the post 6 moths; or recent anticoagulation use were excluded. Patients that due to Paresis or plegia weren't ambulated even though treatment continued excluded from our study. Intervention: After 48 hour of craniotomy for first group Noxprin 40mg (Enoxaparin) made by Alborz Darou Co. daily and subcutaneously and for second group Heparodic (Heparin sulfate) made by Caspian Tamin Co. 5000 IU/12h was used. Main outcome measures: IN both groups Deep Vein Thrombosis as main outcome of both drugs efficacy was evaluated by physical examination and questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102711274N1**
Registration date: **2013-06-08, 1392/03/18**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-06-08, 1392/03/18

Registrant information

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Nourallah Eshraghi

Name of organization / entity

Isfahan Medical University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Drug's price was paid by authors from academic accounts supported by Vice Chancellor for research, University of Medical Science

Expected recruitment start date

2008-07-22, 1387/05/01

Expected recruitment end date

2011-01-20, 1389/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy Comparison of Unfractionated Heparin and Low Molecular Weight Heparin(LMWH) in Deep Vein Thrombosis Prophylaxis for Brain Tumor craniotomy

Public title
Comparison of Heparin and Clexane in Thrombosis Prevention after Craniotomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria : Patients candidate for elective craniotomy due to brain tumor were enrolled in this randomized, double – blinded, controlled clinical trial from 2009 to 2010 in Isfahan IRAN. exclusion criteria : Patients with bleeding into the primary lesion; history of thrombotic events in the post 6 moths; or recent anticoagulation use were excluded. Patients that due to Paresis or plegia weren't ambulated even though treatment continued, excluded from our study.
Age
From **36 years** old to **62 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **154**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double 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 Isfahan Medical University
Street address
Hezar jerib ave, Isfahan Mededical University
City
Isfahan
Postal code
Approval date
2007-07-08, 1386/04/17
Ethics committee reference number
386302

Health conditions studied

1

Description of health condition studied
Deep Vein Thrombosis
ICD-10 code
I 80.2
ICD-10 code description
Phlebitis and Thrombophlebitis of other Deep Vessels of Lower Extremities

Primary outcomes

1

Description
Deep Vein Thrombosis
Timepoint
Before intervention , After intervention daily (from 48 h after operation) until 7 days
Method of measurement
1)Questionnaire, 2)Physical Examination 3) if any doubt remained Doppler Sonography was used

Secondary outcomes

1

Description
Blood Hypertention
Timepoint
Daily Physical Exams
Method of measurement
Daily physical exam

2

Description
Smoking history
Timepoint
Before intervention
Method of measurement
Questionnaire

3

Description
Diabetes Mellitus
Timepoint
Daily Physical Exams
Method of measurement
Lab Data

4

Description
Trombocytopenia
Timepoint
Daily
Method of measurement
Lab Data

Intervention groups

1

Description
intervention group: patients received subcutaneous clexane (40mg/d) 48 hours after craniotomy (Noxparin 40 made by Alborz Darou). treatment continues until patients become mobile or maximum one week.
Category
Treatment - Drugs

2

Description
control group: patients received subcutaneous unfractionated heparin (5000 Iu/12h) Heparodic 5000 made by Caspian Tamin Pharmaceutical Co. 48 hours after craniotomy, treatment continues until patients become mobile or maximum one week.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Azahra Hospital
Full name of responsible person
Dr. Bahram Aminmansour;Associate Professor of Neurosurgery
Street address
Neurosurgery Department, Azahra hospital, Soffeh Ave.
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, University of Medical Sciences
Full name of responsible person
Dr. Peyman Adibi
Street address
Vice Chancellor for Research, Medical university, Hezar Jerib ave, Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty