

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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

###### Name

Nourallah Eshraghi

###### Name of organization / entity

Isfahan Medical University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1250 2664

###### Email address

n\_eshraghi@resident.mui.ac.ir

##### 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 months; 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

#### Contact

##### Name of organization / entity

Isfahan Medical University

##### Full name of responsible person

Nourallah Eshraghi

##### Position

Resident

##### Other areas of specialty/work

##### Street address

Neurosurgery Department, Azahra Hospital, Soffeh ave

##### City

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##### Phone

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n\_eshraghi@resident.mui.ac.ir neshraghi@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Isfahan Medical university

##### Full name of responsible person

Bahram Aminmansour

##### Position

Associate Professor

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

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**Position**

Resident

**Other areas of specialty/work****Street address**

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**Fax****Email**

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**Web page address****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*