

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Prevention of deep vein thrombosis in spinal cord injury, mechanical prophylaxis with or without pharmacological prophylaxes. A randomized controlled trial.

Protocol summary

Summary

The aim of this study is to compare the effects of mechanical prophylaxis with or without pharmacological prophylaxis on prevention of deep vein thrombosis in patients with spinal cord injury. This study is a prospective double blind randomized clinical trial and all patients having the inclusion criteria for this study, randomly will be set in three groups with 25 cases. We will use respectively for first group (Low Molecular Weight Heparin (Enoxaparin) 40mg daily plus compressive stocking), for second group (Unfractionated Heparin 5000 Unit /subcutaneous /two times daily and compressive stocking) and for third group only compressive stocking. Starting from administration of prophylaxis for inpatients, from the first day of hospital stay after hemodynamic stabilizing and will continue until discharge. Inclusion criteria of our study patients are: 1) Patients with spinal cord injury 2) Absence of underlying problems 3) Absence of coagulopathy disorders 4) Renal failure 5) Fractures in other extremities 6) Patients having consent to study. If any case who has fractures in other extremities and underlying problems, will be excluded from the study. Then we will compare the incidence rate of deep vein thrombosis in hospital stay period between these groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111119908N1**
Registration date: **2014-12-01, 1393/09/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-01, 1393/09/10

Registrant information

Name

Mohammad Amin Mohammad Zadeh Gharabaghi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Student Research Committee, Tabriz University Of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prevention of deep vein thrombosis in spinal cord injury, mechanical prophylaxis with or without pharmacological prophylaxes. A randomized controlled trial.

Public title

Prevention of deep vein thrombosis in spinal cord injury, mechanical prophylaxis with or without pharmacological prophylaxes. A randomized controlled trial.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria of patients: Patients with spinal cord injury; Absence of coagulopathy disorders; Renal failure; Fractures in other extremities; Patients having consent to study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 75

Randomization (investigator's opinion)

Randomized

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**

Tabriz University of Medical Sciences

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Tabriz University of Medical Sciences, Golgasht Ave,
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Postal code

51665118

Approval date

2014-01-07, 1392/10/17

Ethics committee reference number

10210101912021

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

spinal cord injury

ICD-10 code

T09.3

ICD-10 code description

Injury of spinal cord, level unspecified

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

Formation of thrombosis in deep veins

Timepoint

Duration of hospital stay period

Method of measurement

Clinical examination and Doppler sonography

Secondary outcomes

empty

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

Low Molecular Weight Heparin 40mg daily plus
compressive stocking

Category

Prevention

2**Description**

Unreactionated Heparin 5000Unit /subcutaneous /two
times daily with compressive stocking

Category

Treatment - Drugs

3**Description**

compressive stocking

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person**Street address****City**

Tabriz

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

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Amin Mohammad Zadeh Gharabaghi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Tabriz 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
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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