

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison the Effect of Aspirin and Enoxaparin on the prevention of deep venous thrombosis in patients with ankle sprain with immobilization of lower extremities in the form of short plaster

Protocol summary

Study aim

Comparison the Effect of Aspirin and Enoxaparin on the prevention of deep venous thrombosis in patients with ankle sprain with immobilization of lower extremities in the form of short plaster

Design

In this research, 195 eligible patients referring to Imam Khomeini Hospital of sari suffering from Ankle sprain were chosen purposefully and were divided into three groups of control and intervention one and two.

Settings and conduct

This study was conducted at Imam Khomeini Hospital and among patients who entered the study according to inclusion criteria. Then, patients will be divided into three groups . the first group (control group), the drug will not be prescribed (the current method in orthopedic and emergency clinics). For the second group, aspirin tablets will be given at a dose of 325 mg daily for 3 weeks. For the third group Enoxaparin; Brand name CLEXANE, 40 mg daily, injected subcutaneously for 3 weeks. Patients will be aware of signs and symptoms of venous thrombosis at the beginning of treatment and will be followed up by the end of the treatment by telephone or in person. After 3 weeks, plaster will be opened and patients will be referred to the laboratory for measuring d-dimer. The lab will not be aware of the patient's therapeutic treatment. Patients with d-dimer levels above 0.2 milligrams per liter will be referred to a collaborator's sonography specialist to investigate the presence of deep vein thrombosis in order to confirm the presence or absence of deep vein thrombosis through Doppler ultrasonography. The sonography specialist is not aware of patient's group of treatment and how much the d-dimer level is. Patients will be examined for the presence of deep vein thrombosis

Participants/Inclusion and exclusion criteria

major inclusion and exclusion criteria: Patients Aged equal

or over 50 years, with ankle sprain Grade 2,3 were included; Patients who have Ankle instability, Ankle medial injury, syndesmosis damage, Wound on the site of injury, The presence of other fractures, People who have an anticoagulant use history were excluded.

Intervention groups

Intervention group one: Aspirin tablet with dose of 325 mg per day for 3 weeks Intervention group two: Enoxaparin, brand name CLEXANE, with a dose of 40 mg daily subcutaneous injection for 3 weeks Control group: No Drugs will be prescribed.

Main outcome variables

D-Dimer value in the D-Dimer test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120726010405N5**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

mehran razavipour

Name of organization / entity

mazandaran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1325 7230

Email address

m.razavipour@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Aspirin and Enoxaparin on the prevention of deep venous thrombosis in patients with ankle sprain with immobilization of lower extremities in the form of short plaster

Public title

Comparison the Effect of Aspirin and Enoxaparin on the prevention of deep venous thrombosis in patients with ankle sprain with immobilization of lower extremities in the form of short plaster

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age greater than or equal to 15 years Ankle Sprain on the lateral side: Grade 2 and 3

Exclusion criteria:

Ankle instability Medial Ankle injury Syndesmosis damage Wound on the site of injury The presence of other fractures People who have an anticoagulant use history

Age

From 15 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 195

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 Mazandaran University of Medical Science

Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moalem Sq., Moalem St., Sari

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2016-09-06, 1395/06/16

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.95.2536

Health conditions studied

1

Description of health condition studied

Sprain of ankle

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

Primary outcomes

1

Description

D-Dimer value in the D-Dimer test

Timepoint

Measurement of D-Dimer Test at before intervention and 21 days after administration of Aspirin and Enoxaparin

Method of measurement

D-Dimer Test kit

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Aspirin Tablets with dose of 325 mg/day for 3 weeks

Category

Treatment - Drugs

2

Description

Second Intervention group: Enoxaparin, brand name of Clexane, with a dose of 40 mg daily subcutaneous injection for 3 weeks

Category

Treatment - Drugs

3

Description

Control group: No drugs

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Doctor Mehran Razavi Pour

Street address

Imam Khomeini Hospital, Amir Mazandarani St., Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3337 7169

Email

m.razavipour@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Doctor Ahmad Ali Enayati

Street address

Deputy of Research and Technology of Mazandaran University of Medical Science, moalem Sq., Moalem St., Sari

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Email

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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

Sari 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr seyed Mehran Razavipour

Position

Hand Surgery

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Mazandaran University of Medical Sciences, First of Vali Asr HWY., Joibar Junction, Emam Sq., Sari

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr seyed Mehran Razavipour

Position

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Doctor Mehdi Mohebbi

Position

Orthopedic resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Mazandaran University of Medical Sciences, First of
Vali Asr HWY., Joibar Junction, Emam Sq., Sari

City

Sari

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available