

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of apixaban and dalteparin in thromboprophylaxis for hematopoietic stem cells transplant recipients

Protocol summary

Study aim

Comparison of apixaban and dalteparin for safe thrombosis prophylaxis in bone marrow transplant recipients

Design

Randomized clinical trial for prophylaxis, two parallel intervention groups, not blinded, On 60 patients divided into two 30-individual groups, block randomization using Excel software.

Settings and conduct

This randomized clinical trial is performed in the bone marrow transplant department of Ayatollah Taleghani hospital on two groups of patients consisting of dalteparin and apixaban recipients. After the catheterization, patients receive anticoagulants and their condition is assessed for thrombosis and bleeding during the hospital stay.

Participants/Inclusion and exclusion criteria

Patients \geq 18 years old, admitted to the bone marrow transplant ward with a khorna score of 2 or higher or a caprini score of 5 or higher, having normal performance, hepatic and renal status

Intervention groups

Intervention group 1: Apixaban 2.5 mg twice daily orally during hospitalization. Intervention group 2: Administration of dalteparin 5000 units per day by subcutaneous injection during hospitalization. Anticoagulants administration will be started after the catheterization and be continued until the platelet count drops to less than 50,000 per microliter.

Main outcome variables

Incidence of thrombosis and bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N25**

Registration date: **2022-01-07, 1400/10/17**

Registration timing: **prospective**

Last update: **2022-01-07, 1400/10/17**

Update count: **0**

Registration date

2022-01-07, 1400/10/17

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaheed Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

mariatavakoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of apixaban and dalteparin in thromboprophylaxis for hematopoietic stem cells transplant recipients

Public title

Comparison of dalteparin and apixaban in thromboprophylaxis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged ≥ 18 years, candidates for bone marrow stem cell transplantation Weight ≥ 40 kg Khorona score ≥ 2 or caprini score ≥ 5 Life expectancy longer than 60 days and performance status score ≤ 2 according to ECOG criteria Creatinine clearance ≥ 30 mL / min Platelet count ≥ 50000 / μ L Liver function test (AST, ALT) below three times the upper limit normal INR ≤ 1.6 No pregnancy

Exclusion criteria:

Bacterial endocarditis Active bleeding, uncontrolled hypertension (SBP > 170 , DBP > 110) Patients receiving haploidentical allogenic transplantation consuming cyclophosphamide Active bleeding in seven days or more before randomization Severe liver disease (known as Childs Pugh cirrhosis class B or C) or kidney disease (creatinine clearance less than 30 ml / min) Known anticoagulation disorder Thrombocytopenia due to previous heparin use

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization using Excel software

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

کمیته اخلاق دانشکده داروسازی دانشگاه علوم پزشکی شهید بهشتی

Street address

Faculty of Pharmacy, Shahid Beheshti University of

Medical Science, Valiasr St., Hashemi Rafsanjani Highway intersection., Tehran, Iran.

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Postal code

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Approval date

2021-12-15, 1400/09/24

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.242

Health conditions studied

1

Description of health condition studied

Thrombosis in bone marrow transplant patients

ICD-10 code

T86.09

ICD-10 code description

Other complications of bone marrow transplant

Primary outcomes

1

Description

Thrombosis

Timepoint

One month (during hospitalization)

Method of measurement

Color doppler sonography

Secondary outcomes

1

Description

Bleeding

Timepoint

One month (during hospitalization)

Method of measurement

Evaluation of patient laboratory factors; Monitoring the patient for signs of bleeding

Intervention groups

1

Description

Intervention group: Apixaban 2.5 mg twice daily orally, starting after catheterization

Category

Treatment - Drugs

2

Description

Intervention group: Dalteparin, 5000 units daily as

subcutaneous injection, starting after catheterization

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleqani hospital

Full name of responsible person

Maria Tavakoli Ardakani

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Tehran, Shahid Chamran Highway, Yemen St., Shahid Arabi St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Tehran, Shahid Chamran Highway, Yemen St., Shahid Arabi St., Building No. 2, Fifth Floor

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maria Tavakoli Ardakani

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Saeid Azimi

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Resident

Latest degree

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Fax**Email**

saeed.azimi92.sa@gmail.com

Web page address**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

Yes - There is a plan to make this available

Title and more details about the data/document

Laboratory findings of patients along with statistical analysis can be shared without providing patients' names.

When the data will become available and for how long

Start 6 months after publication.

To whom data/document is available

Physicians and researchers involved in bone marrow stem cell transplantation Investigations.

Under which criteria data/document could be used

Individuals such as hospital staff or nurses, clinical pharmacists or industry researchers can use the information.

From where data/document is obtainable

Researchers can contact us by email at: saeed.azimi92.sa@gmail.com

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

Submitting an official application from the relevant authorities. Individuals who intend to use the information must be affiliated with reputable organizations and submit their application through these organizations.

Comments