Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of efficacy and adverse effects of rivaroxaban in children with central venous catheter thrombosis

Protocol summary

Study aim
Evaluation of efficacy and adverse effects of rivaroxaban in children with central venous catheter thrombosis
Design
Non-randomized clinical trial without control group Phase 1-2 in 20 patients enrolled between March 2024 and March 2025 and followed for 1 months.
Settings and conduct
In the children's special care department at Tehran Children's Medical Center Hospital, the patient must have been treated with heparin or enoxaparin for at least 5 to 9 days. Then Rivaroxaban drug is prescribed with a dose (according to the table) and continues for 30 days. At the end of 30 days, a compression Doppler ultrasound is performed again. Blinding is not done.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 2-8 years old diagnosed with CVC-VTE by doppler US after receiving at least 5 days of heparin or enoxaparin Exclusion criteria: Age under 2 years, Active bleeding, Comorbidity
Intervention groups
Pediatric patients aged 2 to 18 years with obvious thrombosis with a central venous catheter confirmed by compressive Doppler ultrasonography will be treated as follows: the patient must have been treated with heparin or enoxaparin for at least 5 to 9 days. Then Rivaroxaban drug is prescribed with a dose (according to the table) and continues for 30 days. At the end of 30 days, a compression Doppler ultrasound is performed again.
Main outcome variables
Efficacy and adverse effects of the drug

General information

Reason for update
Acronym
Rivaroxaban trial
IRCT registration information
IRCT registration number: **IRCT20231021059793N1**
Registration date: **2024-02-28, 1402/12/09**
Registration timing: **prospective**

Last update: **2024-02-28, 1402/12/09**
Update count: **0**
Registration date
2024-02-28, 1402/12/09

Registrant information
Name
Azadeh Kiumarsi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8857 9492
Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-03-20, 1403/01/01
Expected recruitment end date
2025-03-21, 1404/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of efficacy and adverse effects of rivaroxaban in children with central venous catheter thrombosis

Public title
Effect of Rivaroxaban in Thrombosis
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 2-18 years old CVC-VTE diagnosed by US Doppler Five days received enoxaparin or heparin

Exclusion criteria:

Active bleeding History of anaphylaxis to rivaroxaban Usage of other anticoagulant drugs including ASA, platelet inhibitors, NSAID, Fibrinolytic, SSRI and SNRI Acutely ill patients with increased risk of bleeding including bronchiectasis, pulmonary cavitation, pulmonary hemorrhage, active cancer, recent HSCT in last 3 months, active GI ulcer or recent GI bleeding in the last 3 months, Liver disease with coagulopathy Patients needing spinal anesthesia or LP Creatinine clearance lower than 30 ml/min Platelet count lower than 75 X 109 Dialysis catheter or artificial heart leaflet Unstable hemodynamic

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Children medical hospital, Gharib st, Keshavarz Blv., Tehran

City

Tehran

Province

Tehran

Postal code

14676783815

Approval date

2023-09-17, 1402/06/26

Ethics committee reference number

IR.TUMS.CHMC.REC.1402.109

Health conditions studied

1

Description of health condition studied

Thrombosis

ICD-10 code

I82

ICD-10 code description

Other venous embolism and thrombosis

Primary outcomes

1

Description

Occurrence of thrombosis

Timepoint

Efficacy of Rivaroxaban is evaluated by Doppler ultrasound conducted 30 days after drug administration.

Method of measurement

Follow-up ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: children with CVC-VTE that would receive 5 days of Enoxaparin and then 30 days of Rivaroxaban.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children medical center

Full name of responsible person

Azadeh Kiumarsi

Street address

Children's Medical Center Hospital, Gharib street, Keshavarz Blvd, Tehran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Akbari Sari

Street address

Research and Technology Vice-Chancellor, 6th floor., Central Organization of the University, Corner of Quds Keshavarz Blvd

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Azadeh Kiumarsi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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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
Participant data sets are to be shared
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
Available for people working in academic institutions
Under which criteria data/document could be used
No other criteria is needed
From where data/document is obtainable
Azadeh Kiumars, Children medical hospital
What processes are involved for a request to access data/document
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Comments