

# 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)

###### Phone

+98 21 8857 9492

###### Email address

akiumarsi@sina.tums.ac.ir

##### 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 10<sup>9</sup> 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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**Phone**

+98 21 6147 0000

**Email**

Akiumarsi@sina.tums.ac.ir

## 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

**City**

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vcr@sina.tums.ac.ir

**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

**Street address**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Azadeh Kiumarsi

**Position**

Assistant professor

**Latest degree**

Subspecialist

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Azadeh Kiumarsi

**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**

akiumarsi@sina.tums.ac.ir

**Comments**