

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of efficacy and safety of dabigatran(paradxa) in pediatric thromboembolism: a pilot study

Protocol summary

Study aim

Evaluation of efficacy and safety of dabigatran(paradxa) in pediatric thromboembolism: a pilot study

Design

clinical trial including two groups receiving Warfarin and oral Dabigatran, With parallel groups, Open lable, notrandomized

Settings and conduct

This study is grounded in the field of thromboembolie in Arak city. After getting informed consent from the parents, demographic information will be recorded. Then the patients divided into two groups receiving warfarin and Dabigatran (for 6 months) not randomly. The incidence of bleeding, recurrent thromboembolism, and kidney-liver function monitored during drug use.

Participants/Inclusion and exclusion criteria

1.Informed consent 2.Children under 18 years 3.Affected by Thromboembolism

Intervention groups

Intervention group: Enoxaparin is given at a dose of 1 mg / kg every 12 hours with Dabigatran(Pradaxa) 220 mg / m2 in a divided doses In the first five days of treatment. Then, enoxaparin is discontinued and Dabigatran(Pradaxa) will continue for 6 months Control group: Enoxaparin is given at a dose of 12 mg / kg every 12 hours with warfarin 0.2 mg / kg once a day In the first five days of treatment. Then, enoxaparin is discontinued and warfarin will continue with an INR of 2-3 for 6 months.

Main outcome variables

incidence of bleeding, recurrent thromboembolism, and kidney-liver function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180711040431N1**

Registration date: **2018-11-23, 1397/09/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-23, 1397/09/02**

Update count: **0**

Registration date

2018-11-23, 1397/09/02

Registrant information

Name

roghaieh rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3322 0099

Email address

r.rahimi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-10, 1397/04/19

Expected recruitment end date

2019-07-10, 1398/04/19

Actual recruitment start date

2018-07-10, 1397/04/19

Actual recruitment end date

2019-07-10, 1398/04/19

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of dabigatran(paradxa) in pediatric thromboembolism: a pilot study

Public title

efficacy and safety of dabigatran(paradxa) in pediatric thromboembolism Referring to Amir Kabir Hospital in

Arak

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Children under 18 years Affected by Thromboembolism

Exclusion criteria:

Having other blood disorders

Age

From **1 year** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

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 Arak University of Medical Sciences

Street address

Amir kabir hospital, Khoram AVE, Arak Town

City

Arak

Province

Markazi

Postal code

38146-7-5999

Approval date

2018-07-10, 1397/04/19

Ethics committee reference number

IR.ARAKMU.REC.1397.082

Health conditions studied

1

Description of health condition studied

children-thromboemboli

ICD-10 code

I74.8

ICD-10 code description

Embolism and thrombosis of other arteries

Primary outcomes

1

Description

bleeding frequency

Timepoint

In the first month, each week and then every month, Primary outcomes are checked.

Method of measurement

Interview with patient or family

2

Description

recurrent thromboembolism

Timepoint

In the first month, each week and then every month, they are checked.

Method of measurement

History and clinical examination and, if needed, imaging

3

Description

liver and kidney function during drug use

Timepoint

In the first month, each week and then every month, they are checked.

Method of measurement

History and clinical examination and, if needed, Liver Function Tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : (received oral Dabigatran), Enoxaparin is given at a dose of 1 mg / kg every 12 hours with Dabigatran(Pradaxa) 220 mg / m2 in a divided doses In the first five days of treatment. Then, enoxaparin is discontinued and Dabigatran(Pradaxa) will continue for 6 months

Category

Treatment - Drugs

2

Description

Control group: Enoxaparin is given at a dose of 12 mg / kg every 12 hours with warfarin 0.2 mg / kg once a day In the first five days of treatment. Then, enoxaparin is discontinued and warfarin will continue with an INR of 2-3 for 6 months.

Category

Treatment - Drugs

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

Amir kabir Hospital

Full name of responsible person

Dr aziz eghbali

Street address

Amir kabir Hospital, Khoram Ave

City

arak

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38146-7-5999

Phone

+98 86 3322 0099

Email

aziz_eghbali@yahoo.com

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

Arak University of Medical Sciences

Full name of responsible person

Dr Aziz eghbali

Street address

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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Aziz eghbali

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

aziz eghbali

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

roghaieh rahimi afzal

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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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

The only data analysis is available to people

When the data will become available and for how long

Get started since 1399

To whom data/document is available

It's free to the public

Under which criteria data/document could be used

It's free to the public

From where data/document is obtainable

aziz_eghbali@yahoo.com

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

Presents presentation

Comments