Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation and comparing the possible side effects of rivaroxaban with warfarin in patients with pulmonary valve replacement or Fontan surgery.

Protocol summary

Study aim
The use of rivaroxaban has fewer possible side effects compared to warfarin.

Design
The clinical trial, with control group, with a parallel group, randomization method in one of the groups, a blind strain, phase 4, on 75 patients and for randomization, a block method is performed with a sealed envelope.

Settings and conduct
In the patients who underwent pulmonary valve replacement, the control group of the group receiving warfarin, the treatment is carried out for 3-6 months and with INR control. In the intervention group receiving rivaroxaban, the treatment is also carried out during the same period of time, and during the treatment period, both groups of patients are followed up in terms of bleeding and thrombotic event, The other group includes 15 patients who have undergone Fontan surgery and have been receiving warfarin for at least 6 months. In these patients, warfarin will be discontinued, when the INR reaches 1.5, rivaroxaban will be started instead, and if tolerated, it will continue for one year. In each patient, the effectiveness and possible side effects including bleeding or thrombotic events caused by rivaroxaban will be compared with similar side effects when receiving warfarin. In the pulmonary valve replacement group, randomization will be done in a block method with a sealed envelope.

Participants/Inclusion and exclusion criteria
1- Obtaining written informed consent (patient or patient's parents) 2- Age 5 to 18 years 3- Performing the Fontan operation or replacing the pulmonary valve 4- Lack of sensitivity and tolerance to Warfarin and rivaroxaba n

Intervention groups
Rivaroxaban use in patients with a history of pulmonary valve replacement and Fontan.

Main outcome variables
Major and minor bleeding; stroke; Thromboembolic events

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054868N2**
Registration date: **2023-11-30, 1402/09/09**
Registration timing: **prospective**

Last update: **2023-11-30, 1402/09/09**
Update count: **0**

Registration date
2023-11-30, 1402/09/09

Registrant information

Name
Mohadese Ghasemi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-12-21, 1403/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparing the possible side effects of rivaroxaban with warfarin in patients with pulmonary valve replacement or Fontan surgery.

Public title

Evaluation the possible side effects of rivaroxaban in patients with pulmonary valve replacement or Fontan surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obtaining informed consent (patient or parents) Age 5-18 years old Performed pulmonary valve replacement or Fontan surgery

Exclusion criteria:

Intolerance or sensitivity to warfarin Intolerance or sensitivity to rivaroxaban

Age

From **5 years** old to **18 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

The identification of patients in terms of age and gender will be done in the PVR group. In this study, randomization will be done by blocked randomization method, using the software, 8 blocks of 8 for the sample size of 60 (30 people in each group) will be calculated for 2 study groups. Each person will be identified with a unique code (consisting of two letters and a Latin number). After obtaining informed consent from the patient and parents, to allocate the patient to each of the 2 groups of the study, an envelope containing a unique code and treatment group will be delivered to the patient or his parents. Before starting the treatment, the associate nurse of the plan will open the envelope and specify the type of intervention.

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 Isfahan University of Medical Sciences- Medical School

Street address

Hezarjerib st, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2023-10-29, 1402/08/07

Ethics committee reference number

IR.MUI.MED.REC.1402.282

Health conditions studied

1

Description of health condition studied

Patients who have undergone pulmonary valve replacement and Fontan surgery.

ICD-10 code

q20.8

ICD-10 code description

Other congenital malformations of cardiac chambers and connections

Primary outcomes

1

Description

Major and minor bleeding

Timepoint

3-6 months. one year

Method of measurement

questionnaire-The tool does not have a specific measurement and is descriptive.

2

Description

Stroke

Timepoint

3-6 months. one year

Method of measurement

questionnaire-The tool does not have a specific measurement and is descriptive.

3

Description
Thromboembolic events
Timepoint
3-6 months. one year
Method of measurement
questionnaire-The tool does not have a specific measurement and is descriptive.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group in patients with a history of pulmonary valve replacement surgery: use of rivaroxaban drug for three to six months after surgery with a dose of: weight over fifty kilos ten milligrams daily, weight thirty to fifty kilos daily seven and a half milligrams daily, Twenty to thirty kilos, two and a half milligrams every twelve hours, ten to twenty kilos, one and seven tenths milligrams every twelve hours, and the manufacturer of Apixaban. Thirty patients
Category
Treatment - Drugs

2

Description
Control group in patients with a history of pulmonary valve replacement surgery: Use of warfarin tablets for 3-6 months with a warfarin dose of one tenth to three tenths of a milligram per kilogram of the patient's weight and with INR control for three to six months after The surgery continues. Thirty patients
Category
Treatment - Drugs

3

Description
Intervention group: There are 15 patients who have undergone Fontan surgery and have been receiving warfarin for the prevention of thromboembolic complications for at least 6 months. In these patients, warfarin will be stopped, and according to existing protocols, when the INR reaches one half, rivaroxaban will be started instead, and if tolerated, it will continue for one year, and side effects will be compared before and after starting rivaroxaban. The dose of warfarin and rivaroxaban is the same for pulmonary valve replacement patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran (Martyr) Hospital
Full name of responsible person
Mohadeseh Ghasemi
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan University of Medical Sciences
Proportion provided by this source
20
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
Esfahan University of Medical Sciences

Full name of responsible person
Mohadeseh Ghasemi

Position
pediatric cardiology fellow

Latest degree
Specialist

Other areas of specialty/work
Cardiology

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

Title and more details about the data/document
Patients who had complications while taking drugs.

When the data will become available and for how long
Unclear

To whom data/document is available
researchers

Under which criteria data/document could be used
Use in other studies

From where data/document is obtainable
executor of plan

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

Comments