Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparing the outcomes of Warfarin consumption compared to Rivaroxaban (Xalerban) in patients with Atrial fibrillation

Protocol summary

Study aim
Comparing the outcomes of Warfarin Consumption Compared to Rivaroxaban (Xalerban) in Patients with Atrial Fibrillation

Design
this phase includes 4, randomized parallel groups clinical trial study. The research units includes 330 individuals. One group will be treated by Warfarin (165) and the other one will be received Rivaroxaban (Xalorban) (165).

Settings and conduct
The research site is Heshmat Hospital in Rasht. Research samples will be followed up by researchers every 15 days in the first month and then every month for 6 month. In this study, a researcher-made checklist will be used to collect demographic data, record liver's enzyme levels, coagulation tests and complications of anticoagulant drugs.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Being over 50 years old, diagnosis of Atrial Fibrillation, CHAD2S2 Vasc score more than 1 exclusion criteria: Patient's dissatisfaction with the study, Wolff Parkinson White Syndrome, allergic to any of the drugs Rivaroxaban (Xalerban) and warfarin, abnormal Creatinine level, and thrombocytopenia.

Intervention groups
In this research, patients are divided to two groups based on random allocation. To prevent atrial fibrillation's complications, patients will be evaluated in two groups of anticoagulant users. A Warfarin-treated group and a Rivaroxaban-treated group (Xalorban). The warfarin group is the control group.

Main outcome variables
Bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170530034232N2**
Registration date: **2019-10-01, 1398/07/09**
Registration timing: **prospective**

Last update: **2019-10-01, 1398/07/09**
Update count: **0**

Registration date
2019-10-01, 1398/07/09

Registrant information

Name
Jalal Kheirkhah

Name of organization / entity
Healthy Heart Research Center of Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 13 3366 4282

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kheirkhah@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-22, 1398/07/30

Expected recruitment end date
2021-01-19, 1399/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the outcomes of Warfarin consumption compared to Rivaroxaban (Xalerban) in patients with Atrial fibrillation

Public title
Outcomes of Warfarin and Rivaroxaban (Xalerban) consumption in patients with Atrial fibrillation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Being over 50 years old Patients with Atrial fibrillation CHAD2S2 Vasc Score more than 1
Exclusion criteria:
Patient's dissatisfaction with the study Wolff Parkinson White Syndrome Allergic to any of the drugs Rivaroxaban (Xalerban) and warfarin Abnormal Creatinine level Thrombocytopenia
Age
From **50 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **330**
Randomization (investigator's opinion)
Randomized
Randomization description
According to the gradual referral of patients to Dr. Heshmat educational and remedial hospital in Rasht, if they meet the inclusion criteria, randomization is planned to be performed using quadruple-block random allocation method in two groups, group A (Warfarin users) and group B (Xalerban users). According to the sample size, the numbers of these blocks are 83, which were selected by lottery at the beginning of the study, stored in a sealed envelope at Healthy Heart Research Center. After the approval of the research plan and starting the study, the selected blocks will be read out daily by a person who is not involved in the study, according to the patient referrals. Then patients will received the drugs based on block’s permutation.
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 Guilan University of Medical Sciences
Street address
Vice-Chancellor For Research and Technology of Guilan University of Medical Sciences, infront of 17 Shahrivar hospital, Shahid Siadati street, Namjoo street, Rasht
City
Rasht
Province
Guilan
Postal code
41446-66949
Approval date
2019-09-07, 1398/06/16
Ethics committee reference number
IR.GUMS.REC.1398.313

Health conditions studied

1

Description of health condition studied
Atrial fibrillation
ICD-10 code
I48.2
ICD-10 code description
Chronic atrial fibrillation

Primary outcomes

1

Description
Bleeding
Timepoint
All patients will be followed up by researchers every 15 days in the first month and then every month for 6 month.
Method of measurement
Measurement of coagulation factors and hemoglobin level by blood test.

Secondary outcomes

1

Description
Changes in liver's enzymes
Timepoint
All patients will be followed up by researchers every 15 days in the first month and then every month for 6 month.
Method of measurement
Measurement of liver's enzymes (SGOT, SGPT) by blood test.

Intervention groups

1

Description
Intervention group: After random allocation, 165 patients

with atrial fibrillation will take one tablet of Rivaroxaban (Xalerban) 20 mg orally, produced by Abidi pharmaceutical company between meal daily for 6 month.

Category

Prevention

2

Description

Control group: After random allocation, 165 patients with atrial fibrillation will take Warfarin produced by Orion corporation pharmaceutical company. The drug dosage will be determined by the physician according to the condition of each patient.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat heart hospital

Full name of responsible person

Dr. Jalal Kheirkhah

Street address

Heshmat Heart Hospital, Mosalla square, Rasht

City

Rasht

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kheirkhah_jalal@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor For Research and Technology of Guilan University of Medical Sciences

Full name of responsible person

Dr. Shadman Nemati

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Vice-Chancellor For Research and Technology, In front of 17 Shahrivar hospital, Shahid Siadati Street, Namjoo Street, Rasht

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research@gums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor For Research and Technology of Guilan University of Medical Sciences

Proportion provided by this source

5

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

2

Sponsor

Name of organization / entity

Dr. Abidi Pharmaceutical Company

Full name of responsible person

Dr. Seyed Amir Razavian Ardahali

Street address

No.72, Abidi square, 8 km Shahid Lashkari highway, Tehran

City

Karaj

Province

Alborz

Postal code

13897-76363

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+98 21 4452 2451

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mohammad.mousavi@cobeldarou.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dr. Abidi Pharmaceutical Company

Proportion provided by this source

95

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Healthy Heart Research Center of Guilan University of Medical Sciences

Full name of responsible person
Dr. Jalal Kheirkhah

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

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Latest degree
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Person responsible for updating data

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Latest degree
Subspecialist

Other areas of specialty/work
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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
Undecided - It is not yet known if there will be 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 SPSS file contains all demographic information (age, sex and body mass index), liver's enzyme information and coagulation tests, and side effects of anticoagulants including: skin complications (ecchymosis and hematoma), gastrointestinal complications (constipation, diarrhea, abdominal pain and nausea). Neurological complications (headache and dizziness), fever, fatigue, edema, pain and muscle spasm, risk of bleeding, TIA and CVA

When the data will become available and for how long
6 month after the results are published, the access period will be start.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

To obtain new results, researchers will be permitted to use further analysis and the data in the future researches.

From where data/document is obtainable

Healthy Heart Research Center, Dr Heshmat heart hospital, Mosalla Square, Rasht, Guilan, Iran Phone number: 00981333664282 P.O.Box: 41939-55588

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

A written request with sufficient detail should be sent to the postal address.After receiving the request, the scientific correspondence author will be responsive within one week.

Comments