

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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)

Phone

+98 13 3366 4282

Email address

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 receive 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

Province

Guilan

Postal code

41939-55588

Phone

+98 13 3366 4282

Email

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

Street address

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

City

Rasht

Province

Guilan

Postal code

41446-66949

Phone

+98 13 3333 5821

Email

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

Phone

+98 21 4452 2451

Email

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

Street address

Healthy Heart Research Center, Heshmat Heart
Hospital, Mosalla square, Rasht

City

Rasht

Province

Guilan

Postal code

41939-55588

Phone

+98 13 3366 4282

Fax

+98 13 3366 8718

Email

kheirkhah_jalal@yahoo.com

Web page address

Person responsible for updating data

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

Street address

Healthy Heart Research Center, Heshmat Heart
Hospital, Mosalla square, Rasht

City

Rasht

Province

Guilan

Postal code

41939-55588

Phone

+98 13 3366 4282

Fax

+98 13 3366 8718

Email

kheirkhah_jalal@yahoo.com

Web page address

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.

Person responsible for scientific 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

Street address

Healthy Heart Research Center, Heshmat heart
hospital, Mosalla square, Rasht

City

Rasht

Province

Guilan

Postal code

41939-55588

Phone

+98 13 3366 4282

Email

kheirkhah_jalal@yahoo.com

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