

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation the effect of aspirin with and without rivaroxaban in lower extremity symptomatic peripheral artery disease in diabetic patient

Protocol summary

Study aim

Determining the effect of aspirin with and without rivaroxaban on symptomatic peripheral vascular disease of the lower extremities of diabetic patients

Design

The clinical trial without blinding; phase 3; randomized according to randomized numbers table with two groups of control (aspirin) and intervention (aspirin + rivaroxaban) on 60 patients, was used for randomization of rand function of Excel software.

Settings and conduct

This study is by randomized control trial and open label. This clinical trial will be performed after the approval of the research plan in the endocrinology clinic of Loghman hospital. Type 2 diabetic patients with symptomatic peripheral vascular disease of the lower extremities are selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetic patients referred to Loghman Hospital endocrinology clinic (with FBS $\geq$ 126, two-hour glucose $>$ 180 and hemoglobin a1c $>$ 6.5%) with symptomatic peripheral vascular disease of the lower extremities (with lameness, lower extremity ulcers and nocturnal pain) Are selected. Exclusion criteria: : Patients taking Clopidogrel, revascularization treatment, joint disorder and hemoglobin a1c larger and equal to 7.5% are excluded from the study

Intervention groups

After selecting the patients and if they are satisfied to participate in the study, they are randomly divided into 2 groups of aspirin users with and without rivaroxaban.

Main outcome variables

Improvement of symptoms and ABI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220502054720N1**

Registration date: **2022-10-30, 1401/08/08**

Registration timing: **retrospective**

Last update: **2022-10-30, 1401/08/08**

Update count: **0**

Registration date

2022-10-30, 1401/08/08

Registrant information

Name

Mohaddese Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8827 0723

Email address

mer3de666@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

2021-09-23, 1400/07/01

Actual recruitment end date

2022-01-20, 1400/10/30

Trial completion date

empty

Scientific title

Evaluation the effect of aspirin with and without rivaroxaban in lower extremity symptomatic peripheral artery disease in diabetic patient

Public title

Evaluation the effect of aspirin with and without rivaroxaban in lower extremity symptomatic peripheral artery disease in diabetic patient

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diabetic type2 patients (FBS > 126 , 2hpp > 180 , HBA1c > 6.5%) lower extremity symptomatic peripheral artery disease

Exclusion criteria:

Patients who used Clopidogrel, revascularization treatment, joint disorder hemoglobin A1C over and equal to 7.5%

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in a simple way for each patient using the website <https://www.randomizer.org>, which is obtained using random numbers extracted by the software, and the patients will be divided into 2 groups receiving A (Aspirin) and B (Aspirin + Rivaroxaban) are allocated. In other words, we extract random numbers according to the number of samples based on the introduced site, in such a way that even numbers are considered for intervention A and odd numbers are considered for intervention B. Patients are assigned to the corresponding group based on whether they received an odd or even number.

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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Yemen Street , Shahid Chamran Highway ,Tehran s

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-05-16, 1401/02/26

Ethics committee reference number

IR.SBMU.MSP.REC.1401.089

Health conditions studied**1****Description of health condition studied**

Type 2 diabetic patients with symptomatic peripheral vascular complications of the lower extremities

ICD-10 code

E11.51

ICD-10 code description

Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene

Primary outcomes**1****Description**

Claudication

Timepoint

At the beginning of the study and 1 and 3 months after taking aspirin with and without rivaroxaban

Method of measurement

Claudication= Fanton criterion and question from the patient

2**Description**

Nocturnal pain

Timepoint

At the beginning of the study and 1 and 3 months after taking aspirin with and without rivaroxaban

Method of measurement

Question from the patient

3**Description**

Wound healing

Timepoint

At the beginning of the study and 1 and 3 months after taking aspirin with and without rivaroxaban

Method of measurement

Observation of the facilitator

4

Description

ABI

Timepoint

At the beginning of the study and 1 and 3 months after taking aspirin with and without rivaroxaban

Method of measurement

Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group includes 30 patients with type 2 diabetes who have peripheral vascular disease of the lower extremities. Patients in this group will receive aspirin (80 mg daily) and rivaroxaban (5.2 mg every 12 hours).

Category

Treatment - Drugs

2

Description

Control group: This group includes 30 patients with type 2 diabetes who have peripheral vascular disease of the lower extremities. Patients in this group will receive only aspirin (80 mg daily).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim hospital

Full name of responsible person

Mohaddese Abbasi

Street address

Loghman Hakim Hospital, Kamali St, South Kargar St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1333625445

Phone

+98 21 5102 5182

Fax

+98 21 5541 6130

Email

Lcrdc@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohaddese Abbasi

Street address

Loghman Hakim Hospital, Kamali St, South Kargar St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1333625445

Phone

+98 21 5102 5182

Email

mer3de666@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

40

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohaddese Abbasi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

No. 67, West Aliyali Ave., Gisha, Tehran town

City

Tehran

Province

Tehran

Postal code

1447774415

Phone
+98 21 8827 0723
Fax
Email
mer3de666@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohaddese Abbasi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No. 67 , West Aliyali Ave., Gisha., Tehran town
City
Tehran
Province
Tehran
Postal code
1447774415
Phone
+98 21 8827 0723
Fax
Email
mer3de666@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohaddese Abbasi

Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No. 67 , West Aliyali Ave., Gisha., Tehran town
City
Tehran
Province
Tehran
Postal code
1447774415
Phone
+98 21 8827 0723
Fax
Email
mer3de666@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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