

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of Need-Based Education on Clinical Outcomes in Patients under treatment with Direct oral anticoagulants (DOACs) drugs in Hospital Affiliated to Shiraz University of Medical Sciences

Protocol summary

Study aim

The effect of Need-Based Education on Clinical Outcomes in Patients under treatment with Direct oral anticoagulants (DOACs) drugs in Hospital Affiliated to Shiraz University of Medical Sciences

Design

Clinical trial with control group, with parallel groups, unblinded, randomized, on 92 patients. The rand function of Excel software will be used for randomization.

Settings and conduct

By referring to Namazi and Shahid Faghih hospitals, two intervention and control groups are randomly selected from among the referring patients who meet the conditions for entering the study, and blinding is not done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being between 18 and 80 years old; Receiving oral anticoagulants; The client's ability to learn the instructions and perform the self-care process. Exclusion criteria: Presence of active bleeding; The presence of mental illnesses and the use of psychotropic drugs according to the patient's statement.

Intervention groups

Intervention group: For the educational group, need-based training in the form of educational pamphlets and face-to-face training will be conducted on the day of the interview, the second and fourth week, in person and by phone. Control group: will only receive the usual training and care.

Main outcome variables

Medication adherence, The international normalized ratio (INR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231204060260N1**

Registration date: **2024-01-24, 1402/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-24, 1402/11/04**

Update count: **0**

Registration date

2024-01-24, 1402/11/04

Registrant information

Name

Fariba Bakhshayesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8355 4810

Email address

faribabakhshayesh815@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Need-Based Education on Clinical Outcomes in Patients under treatment with Direct oral

anticoagulants (DOACs) drugs in Hospital Affiliated to Shiraz University of Medical Sciences

Public title

Effect of Need-Based Education on Clinical Outcomes in Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Being between 18 and 80 years old Receiving oral anticoagulants The client's ability to learn the instructions and perform the self-care process

Exclusion criteria:

Presence of active bleeding The presence of mental illnesses and the use of psychotropic drugs according to the patient's statement

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method will initially be convenience; The samples will then be placed in quadruple blocks by block random sampling. The blockage is usually used to balance the number of samples allocated to each of the studied groups. This feature helps researchers to equalize the number of samples allocated to each of the studied groups in cases where intermediate analyzes are required during the sampling process. All blocks are the same size, and in this two-group experiment, we will have 4 blocks (including 2 participants in the intervention group and 3 participants in the control group). Random allocation software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

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

Valiasr St., Niayesh Highway Intersection, Opposite Shahid Rajaei Heart Hospital, School of Nursing and Midwifery

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-11-13, 1402/08/22

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.153

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

Patients treated with Oral Anticoagulation Drug

ICD-10 code

T45.61

ICD-10 code description

Poisoning by, adverse effect of and underdosing of thrombolytic drugs

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

Prothrombin Time and International Normalized Ratio (PT/INR)

Timepoint

Before and six weeks after the intervention

Method of measurement

Blood test

2**Description**

Medication Adherences

Timepoint

Before and one month after the intervention

Method of measurement

Moriski medication adherence questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For the intervention group, basic and advanced trainings will be implemented based on the need and according to the results of the score obtained from the knowledge questionnaire of anticoagulant drugs. These trainings are related to the time to see a doctor, INR level check periods, the time to apply activity restrictions and the time to return to daily activities, drug side effects, self-care, patients' awareness of the drug, and factors affecting the treatment process with the help of pamphlets and face-to-face training on the interview day. In the second and fourth week, the applicants will receive training by phone.

Category

Other

2**Description**

Control group: will receive only usual training and care.

Category

N/A

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

Namazi Hospital

Full name of responsible person

Fariba Bakhshayesh

Street address

Namazi Square, Zand Street, Shiraz

City

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Province

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7193613311

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2**Recruitment center****Name of recruitment center**

Shahid Faghihi Hospital

Full name of responsible person

Fariba Bakhshayesh

Street address

next to the Faculty of Medicine, Karim Khan Zand Blvd. Shiraz,

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Shahid Chamran Highway, Yemen St. - Shahid Arabi St. next to Ayatollah Taleghani hospital

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fariba Bakhshayesh

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Valiasr St., Niayesh Highway Intersection, Opposite
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahsa Boozaripoor

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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