

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of education to high-risk patients, their families and pre-hospital emergency personnel about strokes on patients' timely referral to the hospital

Protocol summary

Study aim

Determining the effect of training high-risk patients, families and pre-hospital emergency personnel regarding strokes on timely patient referral to the hospital

Design

The clinical trial has intervention and control groups, in a blinded, randomized form, which was used for randomization by lottery and in a random manner.

Settings and conduct

In the selected cluster, based on the files in the comprehensive health service center, all high-risk patients and at least one member of their family will undergo educational intervention. In the case of EMS personnel, the whole number method will also be used.

Participants/Inclusion and exclusion criteria

Entry criteria for high-risk patients and families - Having a record of blood pressure, diabetes or hyperlipidemia in comprehensive health service centers in the city of Shahindej and the villages affiliated to the selected center - Willingness to participate in study and training sessions - Access to a smart mobile phone to join the WhatsApp group to continue and repeat the training - In the case of family members, preferably the person who spends the most hours with the patient will be selected

Intervention groups

According to the clustering, a random cluster will be selected as an intervention group under the educational program, and the other clusters will play the role of the control group.

Main outcome variables

Timely referral of patients, number of calls to EMS, time interval from observing symptoms to calling EMS, time from the onset of symptoms until the patient arrives at the hospital (STD)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230706058688N1**

Registration date: **2023-08-04, 1402/05/13**

Registration timing: **prospective**

Last update: **2023-08-04, 1402/05/13**

Update count: **0**

Registration date

2023-08-04, 1402/05/13

Registrant information

Name

Naseh Soltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4633 2449

Email address

nasehsoltani400@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education to high-risk patients, their families and pre-hospital emergency personnel about strokes on patients' timely referral to the hospital

Public title

Investigating the impact of education on high-risk patients, their families and pre-hospital emergency personnel

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having a record of blood pressure, diabetes or hyperlipidemia in comprehensive health service centers in the city of Shahindej and the affiliated villages of the selected center Willingness to participate in study and training session Access to a smart mobile phone to join the WhatsApp group to continue and repeat the training In the case of family members, the person who spends the most time with the patient will be chosen Being 30 years old or older

Exclusion criteria:

Not having a file as a high-risk patient (hypertension, diabetes, hyperlipidemia)

Age

From **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **1000**

Randomization (investigator's opinion)

Randomized

Randomization description

A cluster sampling method will be used in which one of four urban centers and nearby rural centers will be randomly selected as the intervention group and other centers will be included as the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The intervention group (including high-risk patients and their families in the selected cluster which is selected randomly out of 4 centers in Shahindej city) and the main researcher will know the center which is trained about the timely referral of suspected stroke patients to the hospital. But the data recorders (pre-hospital emergency personnel and emergency ward personnel of Shahin Dej Hospital) are unaware of whether the referred patients are in the intervention group or the control group, and the analyzers also do not know the grouping of the patients.

Placebo

Not used

Assignment

Parallel

Other design features

Community-based randomized trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Working Group / Ethics Committee in Research Faculty of Nursing and Midwifery and Faculty of Rehabil

Street address

9, Shahriar Ave., Shahindej Town

City

Shahindej

Province

West Azarbaijan

Postal code

5981719164

Approval date

2023-07-09, 1402/04/18

Ethics committee reference number

IR.TUMS.FNM.REC.1402.067

Health conditions studied

1

Description of health condition studied

Stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Fast identification and diagnosis

Timepoint

The necessary time periods are about 6 months after the intervention to analyze the obtained data

Method of measurement

The desired variable is quick identification and diagnosis, which will be expressed in minutes from the available documentation

Secondary outcomes

1

Description

timely referal to the hospital,

Timepoint

After the educational intervention, the data will be gathered and analyzed up to 6 months later

Method of measurement

According to the data extracted from the available documents, the time will be calculated in minutes

2

Description

going to hospital by EMS service

Timepoint

After the educational intervention, the data will be gathered and analyzed up to 6 months later

Method of measurement

The ratio of patients admitted with suspected stroke to the hospital through EMS to the total number of patients admitted with suspected stroke

Intervention groups

1

Description

Intervention group: In the case of high-risk patients, the intervention is in the form of educational sessions and using slides in the simple and native language of the region as far as the audience can understand, as well as the use of educational animations in humorous language. Highlighting and answering possible questions will be done to complete the educational process.

Category

Other

2

Description

Intervention group: In the case of pre-hospital emergency personnel, the intervention is in the form of retraining regarding the quick and accurate diagnosis of suspected stroke cases, for this purpose, in addition to the FAST tool, the BEFAST tool and the Iranian IRPSS tool aim to improve diagnosis, inform the hospital and announce the code. Stroke will be used to improve the correct and quick referral of the suspected patient and the time from the onset of symptoms to the transfer of the patient to the hospital. The training of pre-hospital emergency personnel will be done face-to-face and in groups in two two-hour interactive sessions using real scenarios. Then, the important points of the training sessions will be reviewed by sending short reminder messages in the WhatsApp group of medical emergencies, and the personnel will share their experience of using new tools with the aim of solving possible ambiguities.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasi hospital

Full name of responsible person

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2

Recruitment center

Name of recruitment center

Medical emergency center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mehrnaz Geranmayeh

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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
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Position
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Person responsible for updating data

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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

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

Yes - There is a plan to make this available

Title and more details about the data/document

After consultation with the professors and according to the rules of the faculty and ethics committee

When the data will become available and for how long

After consultation with the professors and according to the rules of the faculty and ethics committee

To whom data/document is available

After consultation with the professors and according to the rules of the faculty and ethics committee

Under which criteria data/document could be used

After consultation with the professors and according to

the rules of the faculty and ethics committee

From where data/document is obtainable

After consultation with the professors and according to the rules of the faculty and ethics committee

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

After consultation with the professors and according to the rules of the faculty and ethics committee

Comments