

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of education on Mean blood pressure and drug adherence in patients with hypertensive crisis

Protocol summary

Study aim

The effect of education on mean blood pressure and drug adherence is determined in patients with hypertensive crisis.

Design

This is an interventional study of the type of educational trial that will be conducted on 148 patients with blood pressure crisis who refer to the emergency department of Shahid Modares Teaching Hospital and Social Security Hospital and clinics in Saveh city.

Settings and conduct

Based on random block allocation, patients are placed in one of the intervention (training) or control (routine) groups. Patients are trained in 2 sessions for 20-25 minutes in each session. . At the end of the second, third and fourth weeks at regular intervals, the patient's blood pressure will be taken and recorded again by the administrator and patients' questions will be answered. Patients in the control group will be routinely trained.

Participants/Inclusion and exclusion criteria

Patients are between 18-60 years old. Be able to take care of yourself and take medication Lack of cognitive and psychological problems According to the patient, the patient should not have secondary hypertension. Be literate and speak Persian. Do not have a heart attack, stroke, transient ischemic attack, kidney disorders, heart failure, or be pregnant.

Intervention groups

Patients will be trained in 2 sessions in the first week after the crisis and each session lasts 20-25 minutes. The content of the training related to the definition of normal blood pressure, definition of hypertension, definition of hypertensive crisis, disease causes, risk factors, symptoms, self-care behaviors in hypertension, including diet, proper exercise, medication. At the end, an educational booklet is provided to the patient and his companion.

Main outcome variables

Average blood pressure; drug adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220316054313N1**

Registration date: **2022-08-31, 1401/06/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-31, 1401/06/09**

Update count: **0**

Registration date

2022-08-31, 1401/06/09

Registrant information

Name

nasrin amerehgoli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

n.amerehgoli@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education on Mean blood pressure and drug adherence in patients with hypertensive crisis

Public title
The effect of education on Mean blood pressure and drug adherence in patients with hypertensive crisis

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients should be between 18-60 years old Be able to take care of yourself and take medication Lack of cognitive and psychological problems According to the patient, the patient should not have secondary hypertension. Be literate and speak Persian. Do not have a heart attack, stroke, transient ischemic attack, kidney disorders, heart failure, or be pregnant. Systolic or diastolic blood pressure should be 120/180 or more No financial problems to prepare and use medicine based on the patient's statement. Do not take NSAIDs, glucocorticoids, antidepressants, caffeine, nicotine and licorice Lack of resistance to treatment in a person with high blood pressure
Exclusion criteria:
 Patients who die after training Patients who develop cardiopulmonary arrest after training or need intervention methods (angiography or angioplasty), or surgery (heart, brain ...). Existence of resistance to treatment Administration of any of the NSAIDs, glucocorticoids, antidepressants, caffeine, nicotine and licorice during the study

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **148**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly allocated into intervention and control groups. Blocking is used in order to balance the number of samples allocated to each of the studied groups. The size of all the blocks is equal and in this experiment we will have two groups of 4 blocks (including 2 people in the intervention group and 2 people in the control group). R statistical software is used to prepare the randomization list. Before the start of the study, the randomization list was prepared by the professor of statistics and given to the main researcher. Group A and B were written in the envelopes, respectively, and the researcher opened the envelopes during sampling and as soon as each patient entered. will assign the patient.

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 Arak University of Medical Sciences

Street address

Khatam Al-Anbia University Complex., Basij Sq., Sardasht Town

City

Arak

Province

Markazi

Postal code

3914334911

Approval date

2022-05-22, 1401/03/01

Ethics committee reference number

IR.ARAKMU.REC.1401.066

Health conditions studied

1

Description of health condition studied

Hypertensive crisis

ICD-10 code

I15.8

ICD-10 code description

Other secondary hypertension

Primary outcomes

1

Description

Blood pressure

Timepoint

End of the second, third and fourth week

Method of measurement

Mm Hg using a sphygmomanometer

2

Description

Drug adherence

Timepoint

One month after the intervention

Method of measurement

Girerd Drug Adherence Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For patients in the intervention group, in the first week after the hypertensive crisis, 2 training sessions for 20-25 minutes will be performed in groups of up to 8 people. The patient's mobile number is taken for follow-up. During the study, the patient is called once a week (4 phone calls during the study). In this call, while re-emphasizing the importance of controlling blood pressure and reminding important issues, patients' questions are answered. At the end of the second, third and fourth weeks, patients' blood pressure will be measured and recorded using a mercury sphygmomanometer.

Category

Lifestyle

2

Description

Control group: These patients, like other patients (in the intervention group), will receive the necessary treatments based on the prescription of the treating physician and will receive training that is done routinely by them. At this stage, these patients do not receive the training given by the facilitator to the patients in the intervention group. The blood pressure of these patients is taken and recorded at the end of the second, third and fourth weeks. Will be registered.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical centers under the auspices of Saveh School of Medical Sciences

Full name of responsible person

Nasrin Amerehgoli

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

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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

Arak 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
Arak University of Medical Sciences
Full name of responsible person
Nasrin Amerehgoli
Position
Master student of critical care nursing
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable