

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Investigating the effect of weekly pill box usage on drug adherence in the elderly with cardiovascular disease referring to Kerman Social Security Clinic, 2017

Protocol summary

Study aim

Investigating of the effect of weekly pill box on drug adherence in the elderly with cardiovascular disease

Design

A randomized, controlled, parallel group, single blinded trial on 70 patients with cardiovascular disease

Settings and conduct

Referring to the Kerman Social Security Clinic, eligible patients were enrolled in the study. After completing the demographic and Morisky drug adherence questionnaires, the patients were assigned to the control or intervention groups. In the intervention group, the weekly pill box was provided to the patient and the medications were inserted for one week. The correct way of filling the box was trained to the patient and family member within three next weeks. The control group received routine care. After one month, the drug adherence questionnaire was completed by all patients. Blinding: The statistics analyst blinding was done by coding the groups and not registering any identifiers.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 60 years of age and older Diagnosis of cardiovascular diseases such as hypertension, congestive heart failure, myocardial infarction, acute coronary syndrome, and atrial fibrillation Not having cognitive disorders such as Alzheimer or other types of dementia Physical ability to use the pillbox Exclusion criteria: Hospitalization Unwillingness to continue participating in the study

Intervention groups

Intervention group: Patient's medications were placed in the weekly pill box and training interventions were provided to the patient and his family members about the correct way of filling the box in the next three weeks. Control group: There was no intervention in the control group. After one month, the drug adherence questionnaire was completed by all patients.

Main outcome variables

Medication adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160503027736N5**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **retrospective**

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

shahin heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 5351

Email address

sh.heidari@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-05, 1396/07/13

Expected recruitment end date

2018-02-02, 1396/11/13

Actual recruitment start date

2017-10-12, 1396/07/20

Actual recruitment end date

2018-03-04, 1396/12/13

Trial completion date
2018-03-04, 1396/12/13

Scientific title
Investigating the effect of weekly pill box usage on drug adherence in the elderly with cardiovascular disease referring to Kerman Social Security Clinic, 2017

Public title
Effect of pillbox usage on drug adherence in elderly

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Cardiovascular disease such as hypertension, congestive heart failure, myocardial infarction, acute coronary syndrome, atrial fibrillation Age 60 years or older Ability to use pillbox
Exclusion criteria:
Being hospitalized

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **70**
Actual sample size reached: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are allocated randomly to the intervention or control group. So, code 1 is written on one card and code 2 is written on the other card. Of each sample, 35 cards are issued and qualified persons are assigned to the group by selecting one of the cards. The code one for intervention group and code two was considered as a control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study was single blind and the analyzer was blind to the type of intervention. The blinding was that the data for the intervention group with code 1 and the intervention group data with code 2 were entered into the software without mentioning the type of intervention and were analyzed by an individual outside the research team.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rafsanjan University of Medical Scinces Ethic Comitee

Street address

Rafsanjan University of Medical ScincesImam Ali Blvd,
Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7717643373

Approval date

2017-10-03, 1396/07/11

Ethics committee reference number

IR.RUMS.REC.1396.97

Health conditions studied

1

Description of health condition studied

Drug non-compliance

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug adherence

Timepoint

before intervention- One month after intervention

Method of measurement

Morisky 8 drug adherence questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In this study, there was an intervention group and a control group. In the intervention group, the weekly pillbox, manufactured by the Spadana Medical Technology Company, was used for four weeks. This pill box had a separate transparent chamber for each day and four pillars for medications in the morning, noon, evening and night. The names of weekdays and hours of use of medications were included in each section.

Category

Other

2

Description

Control group: The control group received routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Payambar Azam Hospital clinic

Full name of responsible person

Mrs. Navid Asadi

Street address

Abuhamed street, payambar Azam Hospital, Kerman

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Asadi_navid@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Ali Shamsi

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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

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Shahin Heidari

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ashraf Mehdinia

Position

Clinical Nurse

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Marzieh Loripoor

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Faculty member

Latest degree

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Email

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

Not applicable

Data Dictionary

Not applicable