

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Effect of proactive and retroactive medication reconciliation in the admission time on the reduction of medication error in patients with acute coronary syndrome: a randomized clinical trial study

Protocol summary

Study aim

To assess the effect of proactive and retroactive medication reconciliation in the admission time on the reduction of medication error in patients with acute coronary syndrome

Design

This is a Phase III randomized clinical trial with a control group, in which eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

Settings and conduct

This study will be conducted at the Farshchian Heart Hospital in Hamadan city, involving 162 eligible patients with acute coronary syndrome. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. However, it should be noted that blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 70 years Taking at least 5 medications per day, including medications with high interactions or with a narrow therapeutic window
Exclusion criteria: Discharge in less than 24 hours
Hospitalization in the evening or night shift or on holidays

Intervention groups

Intervention group: In the proactive group, after the patient is hospitalized and before the physician prescribes medication, the researcher prepares a complete history of the patient's medications by referring to the patient's bedside and provides them to the physician in order to prescribe medication according to the obtained medication history. Control group: In the retroactive group, after the patient is hospitalized and the physician prescribes medication, the researcher prepares a complete history of the patient's medications by referring to the patient's bedside, and then the perform medication integration (including the

medications prescribed by the physician and previous medications of the disease).

Main outcome variables

Inconsistencies and medication errors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N494**

Registration date: **2024-01-02, 1402/10/12**

Registration timing: **prospective**

Last update: **2024-01-02, 1402/10/12**

Update count: **0**

Registration date

2024-01-02, 1402/10/12

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-07-21, 1403/04/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of proactive and retroactive medication reconciliation in the admission time on the reduction of medication error in patients with acute coronary syndrome: a randomized clinical trial study

Public title
Effect of proactive and retroactive medication reconciliation in the admission time on the reduction of medication error in patients with acute coronary syndrome

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 70 years Taking at least 5 medications per day, including medications with high interactions or with a narrow therapeutic window
Exclusion criteria:
Discharge in less than 24 hours Hospitalization in the evening or night shift or on holidays

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **162**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets, write "intervention" on one and "control" on the other. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to the intervention or control group.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2023-12-30, 1402/10/09

Ethics committee reference number

IR.UMSHA.REC.1402.624

Health conditions studied

1

Description of health condition studied

Acute coronary syndrome

ICD-10 code

I24.0

ICD-10 code description

Acute coronary thrombosis not resulting in myocardial infarction

Primary outcomes

1

Description

Inconsistencies and medication errors

Timepoint

In the first 24 hours of hospitalization

Method of measurement

By taking history and reviewing the medical record

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the proactive group, after the patient is hospitalized and before the physician prescribes medication, the researcher prepares a complete history of the patient's medications by referring to the patient's bedside and provides them to the physician in order to prescribe medication according to the obtained medication history.

Category

Other

2**Description**

Control group: In the retroactive group, after the patient is hospitalized and the physician prescribes medication, the researcher prepares a complete history of the patient's medications by referring to the patient's bedside, and then the perform medication integration (including the medications prescribed by the physician and previous medications of the disease).

Category

Other

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

Farshchian Heart Hospital in Hamadan city

Full name of responsible person

Mahdiyeh Fateminejad

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Farshchian Heart Hospital, Shahid Fahmideh Ave.

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

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Mahdiyeh Fateminejad

Position

Student of Pharmacology

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

Pharmacologist

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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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