

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Effect of education versus no education on patients' beliefs about medications and their compliance in using them in patients with hyperlipidemia: a double blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the education versus no education on patients' beliefs about medications and their compliance in using them in patients with hyperlipidemia. Design: a double blind randomized clinical trial. Setting and conduct: The eligible patients with hyperlipidemia who will refer to Farshchian Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) age of 18 to 80 years; (b) having hyperlipidemia; (c) indication for statin. Exclusion criteria: (a) using other anti-hyperlipidemia agents simultaneously; (b) history of psychological disorders; (c) history of sensitivity to statin. Intervention group: Routine treatment plus one hour face to face consultation with patients by pharmacologist. Control group: Only routine treatment. Primary outcome: Assessing the patient's compliance about drug instructions using Morisky's questionnaire before and 6 weeks after education. Secondary outcome: Assessing the patient's belief about drug instructions using BMQ questionnaire before and 6 weeks after education. Randomization: Random assignment of the patients to the intervention and control groups one at a time. Blinding: The interviewer who will fill out the questionnaires will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as double blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604119014N95**
Registration date: **2016-04-21, 1395/02/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-21, 1395/02/02

Registrant information

Name

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Name of organization / entity

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University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-04-10, 1395/01/22

Expected recruitment end date

2017-02-22, 1395/12/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of education versus no education on patients' beliefs about medications and their compliance in using them in patients with hyperlipidemia: a double blind randomized clinical trial

Public title

Effect of education versus no education on patients' beliefs about medications and their compliance in using them in patients with hyperlipidemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 18 to 80 years; (b) having hyperlipidemia; (c) indication for statin. Exclusion criteria: (a) using other anti-hyperlipidemia agents simultaneously; (b) history of psychological disorders; (c) history of sensitivity to statin.

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: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization: Random assignment of the patients to the intervention and control groups one at a time.
Blinding: The interviewer who will fill out the questionnaires will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as double blind.

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 the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-04-09, 1395/01/21

Ethics committee reference number

IR.UMSHA.REC.1395.11

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

Hyperlipidemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

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

Assessing the patient's compliance about drug instructions

Timepoint

before and 6 weeks after education

Method of measurement

using Morisky's questionnaire

Secondary outcomes**1****Description**

Assessing the patient's belief about drug instructions

Timepoint

before and 6 weeks after education

Method of measurement

using BMQ questionnaire

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

Routine treatment plus one hour face to face consultation with patients by pharmacologist

Category

Other

2**Description**

Only routine treatment

Category

Other

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

Farshchian Hospital

Full name of responsible person

Mitra Kalvandi

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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

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty