

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 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

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan  
University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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poorolajal@umsha.ac.ir

##### 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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Farshchian Hospital, Shahid Fahmideh Ave

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

School of Pharmacology, Hamadan University of Medical Sciences

**Full name of responsible person**

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice-chancellor for Research the Technology, Hamadan 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**

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**

School of Pharmacology, Hamadan University of Medical Sciences

**Full name of responsible person**

Mitra Kalvandi

**Position**

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Department of Epidemiology

**Full name of responsible person**

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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*