Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

A primary prevention trial of coronary artery disease risk factors modification by using 2013 ACC/AHA guidelines

Protocol summary

Study aim

To evaluate the efficacy of ACC/AHA 2013 guidelines in high risk and low risk individuals

Design

Randomized controlled trial with parallel design Group 1 high risk patients according to Reynold,s Risk score, receiving lifestyle modification based on ACC/AHA guideline and medication Group 2 low risk patients according to Reynold,s Risk score, receiving lifestyle modification based on ACC/AHA guideline Two groups of study have been classified according to Reynold,s Risk scores and there were no random assignment. The clinical trial phase is Phase 2-3

Settings and conduct

A clinical trial with two arms and parallel design allocated 322 participants into intervention arms according to ACC/AHA 2013 guideline. Baseline Reynolds risk score (RRS) allocated study population into low risk RRS≤ 7.5 and high risk group RRS>7.5. Interventions were consisted of life style intervention for low risk arm. High risk group received life style interventions associated with statin (Atorvastatin 20 mg) therapy for individuals with elevated high sensitive C-reactive protein (Hs-CRP). After completion of follow up outcomes were evaluated and compared by repeated measurement analysis.

Participants/Inclusion and exclusion criteria

inclusion criteria: individuals with age above 20 years without history of confirmed CAD exclusion criteria: non compliance

Intervention groups

We allocated life style intervention for low riskReynold,s risk score (RRS) <7.5 arm. High risk RRS>7.5 group received life style interventions associated with statin (Atorvastatin 20 mg) therapy for individuals with elevated high sensitive C-reactive protein (Hs-CRP).

Main outcome variables

change in risk factors level from baseline change in Reynolds risk score from baseline

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181003041218N1**
Registration date: **2018-12-18, 1397/09/27**
Registration timing: **retrospective**

Last update: **2018-12-18, 1397/09/27**
Update count: **0**

Registration date

2018-12-18, 1397/09/27

Registrant information

Name

zinat hatmi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6405 3219

Email address

hatmizn@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2015-04-04, 1394/01/15

Actual recruitment start date

2014-04-04, 1393/01/15

Actual recruitment end date

2015-04-09, 1394/01/20

Trial completion date

2015-09-21, 1394/06/30

Scientific title

A primary prevention trial of coronary artery disease risk factors modification by using 2013 ACC/AHA guidelines

Public title
efficacy of 2013 ACC/AHA guideline in primary prevention of coronary artery disease (CAD)
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
men and women aged over 20 years without previously diagnosed CAD
Exclusion criteria:
non compliance
Age
From **20 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **322**
Actual sample size reached: **322**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Outcome evaluation, data analyzing and monitoring of the project were all blinded.A concealment code has been asigned to each patients, therefore, medical providers who evaluate the risk factor changes according to physical examination and laboratory tests were blinded about patients group of high risk versus low risk one. Moreover,statisticain who analyzed data and project monitoring person were all blinded about study groups.
Placebo
Not used
Assignment
Parallel
Other design features
None

Secondary Ids

1

Registry name
none
Secondary trial Id
none
Registration date
2018-10-20, 1397/07/28

Ethics committees

1

Ethics committee
Name of ethics committee
Medical faculty of Tehran University of medical sciences (TUMS)
Street address
Second floor, Building Number 1 , Purcina Ave, Keshavarz Bulevard, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2014-04-09, 1393/01/20
Ethics committee reference number
1393-25239

Health conditions studied

1

Description of health condition studied
Coronary artery disease
ICD-10 code
I25
ICD-10 code description
Chronic ischemic heart disease

Primary outcomes

1

Description
Mean of systolic blood pressure in mm Hg from baseline
Timepoint
10 months from baseline
Method of measurement
In clinic with standardized sphygmomanometer

2

Description
Mean change in diastolic blood pressure in mm Hg from baseline
Timepoint
10 months from baseline
Method of measurement
In clinic with standardized sphygmomanometer

3

Description
Mean change in total cholesterol in milligram / deciliter from baseline
Timepoint
10 months from baseline
Method of measurement

Laboratory enzymatic method

4

Description
Mean change in fasting blood sugar in milligram / deciliter from baseline
Timepoint
10 months from baseline
Method of measurement
Laboratory enzymatic method

5

Description
Mean change in Reynolds risk score from baseline
Timepoint
10 months from baseline
Method of measurement
statistical calculation method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 : lifestyle modification according to 2013 ACC/AHA guideline in addition to Atorvastatin 20 mg for individual with RRS>7.5 and Hs-CRP>3
Category
Prevention

2

Description
Intervention group2: lifestyle modification according to 2013 ACC/AHA guideline in order to change risk factors level from base
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Noorafshar hospital
Full name of responsible person
Zinat Hatmi
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Noorafshar hospital, Jamalabad street, Niavaran, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Sahraian
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Sixth floor, Ghods Ave, Keshavarz Bulevard, Tehran, Iran
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Grant name
Coronary artery disease risk factor modification based on 2013 ACC/AHA guideline
Grant code / Reference number
25632
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr Zinat Hatmi
Position
Professor

Latest degree
Specialist
Other areas of specialty/work
Cardioprevention
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Just risk factors data without patient,s name
When the data will become available and for how long
After completing the final report and publication of the manuscript
To whom data/document is available
Authors who decides to write a systematic review
Under which criteria data/document could be used
Under copyright roles and regulations
From where data/document is obtainable
Correspondant author of the article
What processes are involved for a request to access data/document
Delivering a research proposal
Comments
Data will be published in the upcoming article