

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 $RRS \leq 7.5$ 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 risk Reynold,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 assigned 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, statistician 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

Street address

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

Street address

Sixth floor, Ghods Ave, Keshavarz Boulevard, 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 scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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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**

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 longAfter 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