

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison the effect of Single Dose (80 mg, Daily) versus Divided Dose (80 mg, BID) of Acetylsalicylic Acid on endothelial function in diabetic patients (Type2): A Randomized Clinical Trial

Protocol summary

Study aim

Comparison of the effect of divided dose Acetylsalicylic Acid (80 milligram, BID) and single dose Acetylsalicylic Acid (80 milligram, daily) on endothelial function in patients with diabetes mellitus

Design

In this open labeled randomized clinical trial, 40 newly diagnosed patients with diabetes mellitus without complication, older than 40 year old and ASCVD score more than 7.5 will enroll. Patients randomly divided into two group using Random Allocation Software. Intervention group will receive Acetylsalicylic Acid, 80 milligram twice and control group will receive Acetylsalicylic Acid, 80 milligram daily, orally. Flow Mediated Dilation will measure in patients just before treatment, one hour after first dose and six days after treatment (one hour before and one hour after last dose).

Settings and conduct

The study will be conducted at Chamran Hospital, Isfahan, Iran. patients who had inclusion criteria, will enroll the study. Flow Mediated Dilation will measure in patients just before treatment, one hour after first dose and six days after treatment (one hour before and one hour after last dose).

Participants/Inclusion and exclusion criteria

Newly diagnosed patients with diabetes mellitus without complication, older than 40 years and ASCVD score more than 7.5

Intervention groups

Intervention group will receive Acetylsalicylic Acid, 80 milligram twice and control group will receive Acetylsalicylic Acid, 80 milligram daily, orally.

Main outcome variables

Flow Mediated Dilation (FMD)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191101045301N1**

Registration date: **2020-02-12, 1398/11/23**

Registration timing: **prospective**

Last update: **2020-02-12, 1398/11/23**

Update count: **0**

Registration date

2020-02-12, 1398/11/23

Registrant information

Name

saeide Bahrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3333 4396

Email address

saeide.bahrani@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Single Dose (80 mg, Daily) versus Divided Dose (80 mg, BID) of Acetylsalicylic Acid on endothelial function in diabetic patients (Type2): A Randomized Clinical Trial

Public title

Comparison the effect of Single Dose versus Divided Dose of ASA on endothelial function in diabetic patients (Type2): A Randomized Clinical Trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 40 year Diabetes Melitus ASCVD Score more than 7.5

Exclusion criteria:

Any cardiovascular disease Any cerebrovascular disease Any cardiac arrhythmia Any anti platelet or anticoagulant consumption Suffering from acute or chronic infection Platelet disturbance or bleeding tendency NSAIDs consumption in recent 14 days Platelet count less than 120000 Smoking Chronic Kidney Disease (CKD) GI Bleeding Pregnancy

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by Random Allocation Software

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

Iran National Committee for ethics in Biomedical Research

Street address

13th floor, Block A, Ministry of Health and Medical Education, Siamey Iran ave.

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2020-01-04, 1398/10/14

Ethics committee reference number

IR.MUI.MED.REC.1398.502

Health conditions studied

1

Description of health condition studied

Newly diagnosed Diabetes mellitus without complication

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Flow Mediated Dilation

Timepoint

Bse line, 1 hour after treatment,6 days after treatment(one hour before last dose), 6 days after treatment(one hour after last dose)

Method of measurement

Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tab ASA, 80 mg, BID, PO (Osve Company, Iran)

Category

Treatment - Drugs

2

Description

Control group: Tab ASA, 80 mg, daily, PO (Osve Company, Iran)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Saeide Bahrani

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Cardiology department office, Chamran Hospital,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooye javanmard

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Teimouri-jervekani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Position

Cardiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

All data will share after removing patients' identification data.

When the data will become available and for how long

Simultaneously with publishing the results

To whom data/document is available

to receive data, researchers need to send request.

Under which criteria data/document could be used

to use in a meta-analysis

From where data/document is obtainable

Sending email to Zahra Teimouri-jervekani Email address: zari.t.j@gmail.com

What processes are involved for a request to access data/document

Formal request from the institute/university is needed to receive data. Contact and personal information are needed.

Comments