

# 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, Siyam 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

**Street address**

Cardiology department office, Chamran Hospital,  
Salman Farsi St.

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3261 1406

**Email**

Saeide.bahrani@resident.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghayegh Haghjooye javanmard

**Street address**

Isfahan University of Medical Sciences, Hezar jarib  
Ave., Isfahan

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**Phone**

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**Email**

research@mui.ac.ir

**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**

Cardiology

**Street address**

Cardiology department office, Chamran Hospital,  
Salman Farsi St., Isfahan

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**Email**

zari.t.j@gmail.com

## Person responsible for scientific inquiries

### Contact

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**Position**

Associate professor

**Latest degree**

Specialist

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Position**

Cardiology Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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**