

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Effect of botulinum toxin injection versus placebo injection in fat pad around the heart on the incidence of intra-hospital atrial fibrillation after coronary artery bypass graft (CABG): a single-blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of botulinum toxin injection versus placebo injection in fat pad around the heart on the incidence of intra-hospital atrial fibrillation after coronary artery bypass graft (CABG)

##### Design

This is a single-blind randomized clinical trial, phase II, in which 60 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible patients undergoing coronary artery bypass graft referring to the Farshchian Heart Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 80 years, Indication of coronary artery bypass graft Exclusion criteria: History of previous heart surgery, Unstable angina or heart failure, Chronic atrial fibrillation, Aortic or mitral valvular disease, Liver or renal or thyroid disorder, Taking anti-arrhythmic medications

##### Intervention groups

Intervention group: Injection of Botulinum Toxin Type A (manufacture by Dysport Co.) 50 U with insulin needle in fat pad around the heart single does Control group: Injection of serum normal saline 0.9% one U with insulin needle in fat pad around the heart single does

##### Main outcome variables

Primary outcome: Intra-hospital atrial fibrillation after coronary artery bypass graft

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N338**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **prospective**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

##### Registration date

2020-02-01, 1398/11/12

##### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-20, 1398/12/01

##### Expected recruitment end date

2020-05-20, 1399/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
Effect of botulinum toxin injection versus placebo injection in fat pad around the heart on the incidence of intra-hospital atrial fibrillation after coronary artery bypass graft (CABG): a single-blind randomized clinical trial

**Public title**  
Effect of botulinum toxin injection versus placebo injection in fat pad around the heart on the incidence of intra-hospital atrial fibrillation after coronary artery bypass graft (CABG)

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Age of 18 to 80 years, Indication of coronary artery bypass graft

**Exclusion criteria:**  
History of previous heart surgery, Unstable angina or heart failure, Chronic atrial fibrillation, Aortic or mitral valvular disease, Liver or renal or thyroid disorder, Taking anti-arrhythmic medications

**Age**  
From **18 years** old to **80 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The drug and placebo are prescribed through injection and their shapes are perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

**Placebo**  
Used

**Assignment**  
Parallel  
**Other design features**

**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 and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**  
Hamadan

**Province**  
Hamadan

**Postal code**  
6517838695

**Approval date**  
2020-01-25, 1398/11/05

**Ethics committee reference number**  
IR.UMSHA.REC.1398.950

**Health conditions studied**

1

**Description of health condition studied**  
Atrial fibrillation

**ICD-10 code**  
I48.91

**ICD-10 code description**  
Unspecified atrial fibrillation

**Primary outcomes**

1

**Description**  
Intra-hospital atrial fibrillation after coronary artery bypass graft

**Timepoint**  
Daily for 7 to 10 days

**Method of measurement**  
With monitoring machine

**Secondary outcomes**  
empty

**Intervention groups**

## 1

### Description

Intervention group: Injection of Botulinum Toxin Type A (manufacture by Dysport Co.) 50 U with insulin needle in fat pad around the heart single does

### Category

Treatment - Drugs

## 2

### Description

Control group:

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Farshchian Heart Hospital in Hamadan city

#### Full name of responsible person

Hosna Mohebi

#### Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Phone

+98 81 3838 1740

#### Email

gp.mohebi@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr. Saeid Bashirian

#### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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#### Phone

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#### Email

info.research@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

#### Full name of responsible person

Hosna Mohebi

#### Position

Medical Student

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Practitioner

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School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Hamedan University of Medical Sciences

#### Full name of responsible person

Dr. Farzad Emami

#### Position

Cardiologist

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Cardiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
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Dr. Jalal Poorolajal  
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Professor of Epidemiology  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Epidemiology  
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poorolajal@umsha.ac.ir

## 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

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