Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 songle-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 hear 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)

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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 songle-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 hear 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

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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
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Sponsors / Funding sources

1

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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
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
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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
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