

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 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 open-heart surgery: a double-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 open-heart surgery

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 open-heart surgery 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 open-heart surgery 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, left ventricular ejection fraction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N350**

Registration date: **2020-03-28, 1399/01/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-28, 1399/01/09**

Update count: **0**

Registration date

2020-03-28, 1399/01/09

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-09-21, 1399/06/31

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 open-heart surgery: a double-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 open-heart surgery: a double-blind randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 80 years, Indication of open-heart surgery

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

2020-03-01, 1398/12/11

Ethics committee reference number

IR.UMSHA.REC.1398.1062

Health conditions studied**1****Description of health condition studied**

Atrial fibrillation

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

Primary outcomes**1****Description**

Intra-hospital atrial fibrillation after open-heart surgery

Timepoint

Daily for 7 to 10 days

Method of measurement

With monitoring machine

2**Description**

Left ventricular ejection fraction

Timepoint

Before open-heart surgery and one month after that

Method of measurement

Using echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

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

Category

Treatment - Drugs

2

Description

Control group: Injection of serum normal saline 0.9% one unit with insulin needle in fat pad around the heart single does

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.

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6517838695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

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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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

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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