Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 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 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 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, 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
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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 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
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
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Sponsors / Funding sources

1

Sponsor
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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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Person responsible for updating data

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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