Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of high dose corticosteroid regimen for treatment of postoperative high degree Atrioventricular block after valvular cardiac surgery ; A single blind randomized clinical trial

Protocol summary

Study aim

Evaluation of the efficacy of short-term high-dose steroid treatment regimen in recovery time-frame of advanced AV blocks following heart valve surgeries

Design

Each subject has a unique identification code .Demographic features and history of underlying diseases will be obtained from medical history and lab data. This clinical trial is a phase 3 investigation. Prior assessments indicate to the chance of spontaneous recovery of AV block after 5 and 7 days of surgery about 80 and 94 % ,respectively. The target or clinical outcomes defined as achieving the goal of 7 days recovery within a 5 day cut point. The sample size calculated based on an alpha error of 0.05 and power estimate of 80 % was 150 subjects with 75 patients in each group.

Settings and conduct

The present study will be conducted in surgery associated wards of Tehran heart center

Participants/Inclusion and exclusion criteria

Presence of advanced atrioventricular block following heart valve surgery including valve replacement or repair with or without CABG; Exclusion of patients having cardiac pacemakers ,ICD or CRT ; prior advanced AV block; recent myocardial infarction or CPR during last week ; diabetics with uncontrolled hyperglycemia ; patients with active infections;immune deficiency ; patients with history of hypersensitivity to steroids; persistent or permanent atrial fibrillation

Intervention groups

Therapeutic intervention is defined as administration of 0.4 mg per kg of intravenous dexamethasone (maximum dose of 35 mg per day) with divided regimen for 3 consecutive days. Standard treatment (for controls) is close observation accompanied with TPM support for all patients(if necessary).

Main outcome variables

1.Frequency of recovery of AV block 5 days after cardiac surgery in percents 2. Comparison of the time of AV block between 2 groups (hours)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180430039488N1**
Registration date: **2019-03-28, 1398/01/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-28, 1398/01/08**
Update count: **0**

Registration date

2019-03-28, 1398/01/08

Registrant information

Name

Farzad Masoudkabir

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8802 9600

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-25, 1398/01/05

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of high dose corticosteroid regimen for treatment of postoperative high degree Atrioventricular block after valvular cardiac surgery ; A single blind randomized clinical trial

Public title

Efficacy of steroid treatment on heart blocks secondary to heart valve surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of advanced atrioventricular block following heart valve surgery including valve replacement or repair with or without CABG Written documented informed consent

Exclusion criteria:

Exclusion of patients having cardiac pacemakers or intracardiac defibrilator-cardiovertor or CRT Exclusion of subjects having prior advanced AV block with underlying congenital or acquired etiologies or known brady-arrhythmia Exclusion of patients with acute or recent myocardial infarction or CPR during last week (or survivors of aborted sudden cardiac death) Exclusion of diabetics with uncontrolled hyperglycemia (BS>200 in 2 or more measurements out of 4 samples during last 24 hours or HbA1C>9, ketoacidosis or hyperglycemic hyperosmolar state) Exclusion of patients with active infections Exclusion of patients with immune deficiency disorders including malignancies and HIV-AIDS,.... Exclusion of patients with prior history of hypersensitivity reactions to steroids Exclusion of patients with persistent or permanent atrial fibrillation (AF for more than 24 hours except transient or paroxysmal cases)

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

permuted block randomization containing 4 subjects in each block eg : AABB. A refers to intervention group and B refers to controls.

Blinding (investigator's opinion)

Single blinded

Blinding description

Collected data of the study will be entered in the SPSS and then analysed by an independent expert from THC research institute.

Placebo

Not used

Assignment

Parallel

Other design features

patients in control group receive standard medical care including TPM and monitoring while the others in intervention group receive corticosteroid regimen in addition to standard treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Ghods.street, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

3135674193

Approval date

2018-09-08, 1397/06/17

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.403

Health conditions studied

1

Description of health condition studied

Advanced atrioventricular block following heart valve surgery

ICD-10 code

144.1

ICD-10 code description

Atrioventricular and left bundle-branch block

Primary outcomes

1

Description

Frequency or recovery of AV block

Timepoint

5days

Method of measurement

Duration of AV block in hours and percentage of recovery after 5 days.

Secondary outcomes

1

Description
Incidence rate of of PPM implantation
Timepoint
One month
Method of measurement
Observation and follow-up.Percentage of patients in each group who ultimately undergone PPM implantation

Intervention groups

1

Description
Intervention group: Administration of intravenous dexamethasone with dose of 0.4 mg per kg (maximum dose of 35 mg per day) in divided schedule for 3 consecutive days. All patients including control group have the support of temporary pacemaker and standard conservative treatments.
Category
Treatment - Drugs

2

Description
Control group: This group will receive standard treatment protocol including close monitoring of rhythm with support of a Temporary pace maker
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran heart center
Full name of responsible person
Farzad Masoudkabir
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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
Tehran Heart Center
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
Tehran University of Medical Sciences
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Position
Assistant professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Particular parts of the data will be released
When the data will become available and for how long
After release of the results
To whom data/document is available
Scientific institutions
Under which criteria data/document could be used
Further analysis
From where data/document is obtainable
Dr Saeed Ghodsi
What processes are involved for a request to access data/document
Formal or official request by an institution
Comments