

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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 Masoudkabar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8802 9600

##### Email address

fmasoudkabar@sina.tums.ac.ir

##### 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 defibrillator-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 Masoudkabar

#### Street address

Jala-al-ahmad highway- North Kargar street

#### City

Tehran

#### Province

Tehran

#### Postal code

3135674193

#### Phone

+98 21 8802 9600

#### Fax

#### Email

fmasoudkabar@sina.tums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran Heart Center

#### Full name of responsible person

Saeed sadeghian MD

#### Street address

Jala-Al-ahmad highway .North Kargar street

#### City

Tehran

#### Province

Tehran

#### Postal code

3135674193

#### Phone

+98 21 8802 9600

#### Email

fmasoudkabar@sina.tums.ac.ir

### 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

#### Full name of responsible person

Farzad masoud kabir

#### Position

Assistant professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Cardiology

#### Street address

North Kargar street,Jala-AL ahmad highway-

#### City

Tehran

#### Province

Tehran

#### Postal code

3135674193

#### Phone

+98 21 8802 9600

#### Email

Fmasoudkabar@sina.tums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Saeed Ghodsi

**Position**

Cardiology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

**Street address**

Jala-AL ahmad highway- North Kargar street

**City**

Tehran

**Province**

Tehran

**Postal code**

3135674193

**Phone**

+98 21 8802 9600

**Email**

Dsaeedgh@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Saeed ghodsi

**Position**

Cardiology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

**Street address**

North Kargar street Jala-AL ahmad highway-

**City**

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**Province**

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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**