

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of target control injection (TCI) of anesthetic with conventional method on creatinine level of patients with renal impairment in open heart surgery

Protocol summary

Study aim

Comparison of the effect of target control injection (TCI) of anesthetic with conventional method on creatinine level of patients with renal impairment in open heart surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 66 patients. In order to randomize, the block randomization method will be used.

Settings and conduct

In this study, all patients needed open heart surgery with renal impairment who referred to Rajai Hospital will be enrolled. Patients will be randomly divided into 3 groups based on 6 blocks. The sample size for each study group is 22. A total of 66 patients will be examined. Patients, surgeon and data analyzer will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidates for open heart surgery who have creatinine greater than 1.5 mg / dl; patients over 18 years. Exclusion criteria: Patients over 70 years; pregnancy.

Intervention groups

First intervention group: For anesthesia of patients with targeted controlled injection, Remy Fentanyl with a dose of 0.5 - 1 µ/kg, propofol with a dose of 2 - 2.5 mg/kg and then Atra with a dose of 0/15 - 0/2 mg/kg will be used. Second intervention group: for anesthesia of patients from Midazolam with a dose of 0.2 - 0.4 mg/kg, Fentanyl with a dose of 2-20 µg/kg and Atra with a dose of 0.005 - 0.01 mg/kg/min Will be infused continuously. Control group: For patients undergoing conventional anesthesia, Remi Fentanyl at a dose of 0.5-1 µ/kg, Propofol at a dose of 2 -2/5 mg/kg, and then Atra at a dose of 0.15 - 0.2 mg/kg will be used.

Main outcome variables

Total dose of anesthesia; Creatinine levels; Duration of

hospitalization in the ICU

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151003024317N11**

Registration date: **2020-07-11, 1399/04/21**

Registration timing: **prospective**

Last update: **2020-07-11, 1399/04/21**

Update count: **0**

Registration date

2020-07-11, 1399/04/21

Registrant information

Name

Mahdi Rezai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8868 6772

Email address

rezaei.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-20, 1399/04/30

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of target control injection (TCI) of anesthetic with conventional method on creatinine level of patients with renal impairment in open heart surgery

Public title

The Effect of Target Control Infusion (TCI) on the Creatine Level of Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are candidates for open heart surgery who have creatinine greater than 1.5 mg / dl Patients over 18 years old

Exclusion criteria:

Patients over 70 years Pregnancy

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to tree groups. In order to randomize, a random block method will be used. For this purpose, we formed blocks of size 6. In each block, 2 individuals will be in intervention group 1, 2 individuals will be in intervention group 2 and 2 will be in control group. A total of 11 blocks will be considered for the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Surgeons and patients will be kept blind and unaware of the type of anesthesia. Patients will be aware that they will be randomly assigned to one of three treatment groups, but will be unaware of which treatment will be provided in that group. Patients will be assigned to one of three groups using random number tables. The surgeon also knows that patients will be anesthetized in three different ways, but will not know which procedure will be performed for each patient. The data collection officer, analyst, outcome assessor and data safety and Data Safety and Monitoring Committee will collect and analyze information based on groups 1, 2 and 3 and will not be aware of the type of treatment provided in the groups. They will be kept blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-05-16, 1399/02/27

Ethics committee reference number

IR.IUMS.FMD.REC.1399.130

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

Renal impairment in open heart surgery

ICD-10 code

I97.1

ICD-10 code description

Other functional disturbances following cardiac surgery

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

Total dose of anesthesia

Timepoint

After surgery

Method of measurement

Based on patient records

2**Description**

Creatinine levels

Timepoint

During surgery, After surgery, 24 hours after surgery

Method of measurement

Based on patient records

3

Description

Duration of hospitalization in the ICU

Timepoint

During patient discharge

Method of measurement

Based on patient records

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: For anesthesia of patients by targeted controlled injection, Remy Fentanyl with a dose of 0.5-1 μ /kg (manufacturer: NORMON,SA(spain)), propofol with a dose of 2 - 2.5 mg/kg (manufacturer: BRUN/B) and Cis Atracurium (Manufacturer: Behin Tamin Rosa Mod Co.) at a dose of 0.15-0.2 mg/kg will be injected. Then, depending on the depth of anesthesia, the drug will be injected and whenever the number of BIS reaches between 40 and 60, the patient will be intubated and in order to maintain anesthesia, propofol with a dose of 2-3 μ /ml in patients over 50 years or 3-4 μ /ml in Patients under 50 years, Remy Fentanyl with a dose of 3-6 ng/ml in patients over 50 years and 5-8 ng/ml in patients less than 50 years and finally Cis Atracurium with a dose of 3 μ / kg/min will be prescribed with TCI technique.

Category

Treatment - Drugs

2

Description

Second intervention group: for anesthesia of patients from Midazolam with a dose of 0.2 - 0.4 mg/kg (manufactured by Exir Company), Fentanyl with a dose of 2-20 μ g/kg (manufactured by Caspian Tamin Rasht Factory) and Atracurium with a dose of 0.005 - 0.01 mg/kg/min (manufactured by Abu Reihan Company) Will be infused continuously.

Category

Treatment - Drugs

3

Description

Control group: For patients undergoing conventional anesthesia, Remy Fentanyl with a dose of 0.5-1 μ /kg (manufacturer: NORMON,SA(spain)), propofol with a dose of 2 - 2.5 mg/kg (manufacturer: BRUN/B) and Cis Atracurium (Manufacturer: Behin Tamin Rosa Mod Co.) at a dose of 0.15-0.2 mg/kg will be injected. Then, depending on the depth of anesthesia, the drug will be injected and whenever the number of BIS reaches between 40 and 60, the patient will be intubated and in order to maintain anesthesia, propofol with a dose

of 2-3 μ /ml in patients over 50 years or 3-4 μ /ml in Patients under 50 years, Remy Fentanyl with a dose of 3-6 ng/ml in patients over 50 years and 5-8 ng/ml in patients less than 50 years and finally Cis Atracurium with a dose of 3 μ / kg/min will be injected with a regular pump.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Nazanin Ahmadi

Street address

Rajaie Cardiovascular Medical and Research Center, Next to Mellat Park, Vali-e-Asr St.

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Fax

Email

info@rhc.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abbas Motevallian

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

research@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mohsen Ziyaei Fard
Position
Associate Professor of Anesthesia and Special Care
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Rajaie Cardiovascular Medical and Research Center,
Next to Mellat Park, Vali-e-Asr St.
City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 23921
Email
mziyaeifard@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohsen Ziyaei Fard
Position
Associate Professor of Anesthesia and Special Care
Latest degree
Specialist
Other areas of specialty/work
Biochemistry
Street address
Rajaie Cardiovascular Medical and Research Center,

Next to Mellat Park, Vali-e-Asr St.
City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 23921
Email
mziyaeifard@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohsen Ziyaei Fard
Position
Associate Professor of Anesthesia and Special Care
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Rajaie Cardiovascular Medical and Research Center,
Next to Mellat Park, Vali-e-Asr St.
City
Tehran
Province
Tehran
Postal code
1995614331
Phone
+98 21 23921
Email
mziyaeifard@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty