

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparing the Effects of Isoflurane-Sufentanil Anesthesia and Propofol-Sufentanil Anesthesia on Serum Cortisol Levels in Open Heart Surgery with Cardiopulmonary Bypass

Protocol summary

Summary

Objectives:The aim of this study is to compare the effects of propofol and isoflurane, both supplemented with sufentanil, on the stress response in coronary artery bypass grafting surgery with cardiopulmonary bypass, using cortisol as a biochemical marker **Design:** This double-blind randomized clinical trial will conduct on patients who undergo CABG surgery after obtaining the informed consent and approved by the Institutional Ethics Committee of Guilan University of Medical Science. **Setting and Conduct:** Because of maximum cortisol level occurs in early morning , All samples will take on the morning between 7:30 am to 8:30 am. **Participants:** Inclusion criteria: 72 patients classified upscale 65-18 year old, physical status (ASA class) II-III, in year between 2014-2015 ,who underwent elective bypass surgery after coronary artery disease (3 vessels) with cardiopulmonary pump will enroll in the study . In any case of following problem the patients don't meet the inclusion criteria, they don't enter into study: emergency surgery, liver-kidney disease, neurology, diabetes, thyroid, use of corticosteroids and other drugs that suppress the immune , obesity (BMI \geq 30), addiction to alcohol and drugs. **Exclusion criteria:** Any complication during surgery, bleeding, arrhythmia resistant to conventional treatment, duration of contact pump over 100 minutes, hematocrit less than 25%, intubation prolonged intensive care unit, drug use(sympathomimetic) to disconnect the patient from the pump (epinephrine, norepinephrine) and the use of IABP patients were excluded from the study. **Intervention:** This study will perform in double blind setting and the patients will randomly allocate to select the cards I (isoflurane group) or cart P (propofol group) to receive(isoflurane-sufentanil) or (Propofol-sufentanil). **outcome variable :**Levels of blood cortisol will measure half an hour before transfer to the operating room and given

premedication (T0), after heart-lung pump (T1) and 24 hours after the surgery (T2).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071713456N5**

Registration date: **2015-09-14, 1394/06/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-14, 1394/06/23

Registrant information

Name

Abbas Sedighinejad

Name of organization / entity

Guilan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Guilan University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2015-12-06, 1394/09/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the Effects of Isoflurane-Sufentanil Anesthesia and Propofol-Sufentanil Anesthesia on Serum Cortisol Levels in Open Heart Surgery with Cardiopulmonary Bypass

Public title
Comparing the Effects of Isoflurane-Sufentanil Anesthesia and Propofol-Sufentanil Anesthesia on Serum Cortisol Levels in Open Heart Surgery

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion Criteria:72 patients 18-65 years old with ASA classII-III who undergo CABGs with cardiopulmonary bypass; All samples will take on the morning between 7:30 am to 8:30 am. Exclusion Criteria : Emergency surgery; Hepatic or Renal failure; Neurologic Disorders; Diabetes; Malignancies; BMI>38 kg/m2; Steroid therapy before operation; Chronic Drug abuse; Thyroid dysfunction and Redo operation; sever hemorrhage ; arrhythmia resistant to treatment ;time of CPB over than 100 min ; Hct<25%;prolonged intubation in ICU; use of sympathomimetic drug to treat or help IABP and weaning(epinphrine ,norepinephrine)

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Comeetee of Guilan University of Medical Sciences

Street address

Deputy department, Namjoo Avenue

City

Rasht

Postal code

4193833697

Approval date

2014-02-22, 1392/12/03

Ethics committee reference number

1920422816

Health conditions studied

1

Description of health condition studied

Cronary Artery Disease Three Vessel Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease Coronary (artery): atherosclerosis

Primary outcomes

1

Description

Blood Cortisol Level

Timepoint

Preoperative ,cardiopulmonary Bypass,24 hour after surgery

Method of measurement

the blood cortisol level mcg/litr

Secondary outcomes

1

Description

Mean Arterial Pressure (mmhg)

Timepoint

Preoperative,During CPB and After 24 hours)

Method of measurement

with monitoring of blood pressure

Intervention groups

1

Description

In I group anesthesia will maintaine with 1-1.5% of volatile anesthetitc , isoflurane and sufentanil 0.1-0.3 µg/kg/h and 0.6 mg/kg/h cisatracurium.

Category

Treatment - Drugs

2

Description

In P group anesthesia will maintain by continuous infusion of propofol 50-150 mg/kg/min isoflurane and sufentanil 0.1-0.3 µg/kg/h and 0.6 mg/kg/h cisatracurium.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Heshmat ,the Heart hospital ,Teaching and Research Center

Full name of responsible person

Dr Abbas Sedighinejad

Street address

DR Heshmat hospital,Bayani Crossroad,shahid Beheshti Hiway.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellaor for Research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heydarzadeh Dr

Street address

GAZ square,the first of shahid Beheshty high way.

City

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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

Vice Chancellaor for Research of Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Abbas Sedighinejad

Position

Associated Professor

Other areas of specialty/work

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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