

# 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

Iran (Islamic Republic of)

##### Phone

+98 911 132 5712

##### Email address

a\_sedighinejad@gums.ac.ir

##### 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

Rasht

## 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

Rasht

##### 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

#### Street address

Anesthesiology Research Centre,velayat hospital,,Crossroads Poursina,Namjoo st.

#### City

Rasht

#### Postal code

4193713189

#### Phone

+98 13 1321 0434

#### Fax

#### Email

a\_sedighinejad@yahoo.com;

a\_sedighinejad@gums.ac.ir

#### Web page address

## Person responsible for scientific 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

#### Street address

Anesthesiology Research Center,Velayat hospital,crossroad poursina Rasht

#### City

Rasht

#### Postal code

4193713189

#### Phone

+98 13 1321 0434

#### Fax

#### Email

a\_sedighinejad@yahoo.com;a\_sedighinejad@gums.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Guilan University of Medical Sciences

#### Full name of responsible person

Mohammad Haghighi

#### Position

Associated Professor

#### Other areas of specialty/work

#### Street address

Anesthesiology Research Center,Velayat Hospital,Crossroad Poursina.

#### City

Rasht

**Postal code**

**Phone**

+98 139113315256

**Fax**

**Email**

manesthesist@gmail.com

**Web page address**

## 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*