# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparative study of the effect of propofol infusion before injection of induction dose on injection induced pain and changes in serum complement in patients candidate for general anesthesia

## Protocol summary

**Study aim**

The purpose of this study is to evaluate the effect of propofol infusion before administration of propofol induction dose on injection pain and changes in serum complement.

**Design**

In this study, 60 surgical patients undergoing general anesthesia are selected and randomly divided into three groups. Two intervention groups and one control group.

**Settings and conduct**

The purpose of this study is to evaluate the effect of propofol infusion before administration of the induction dose of propofol on injection pain and changes in serum complement.The design of the study is single blinded and the patient is unaware of how the intervention is conducted by the researcher. Sampling is carried out at Firoozgar Educational Center. Sample size is about 60 people.Group A is being studied as a control group and injection of induction dose is carried out without propofol infusion.In the other two groups, the intervention is administered with propofol infusion with two different doses before injection of the induction dose. Two minutes before induction of anesthesia with propofol, in group B, 50 micrograms per kg of weight per minute, and in group C, 100 micrograms per kg of body weight per minute, propofol is infused for one minute. In all three groups, a blood sample is taken at the time of IV catheterization and one specimen, one minute after injection of propofol induction dose from the same hand and above the injection site to measure the serum level of complement C3 factor. Also, when injected, the degree of pain induced by injection is evaluated using VAS.

**Participants/Inclusion and exclusion criteria**

All patients with ASA I & II physical conditions aged between 18 and 60 years old who are candidates for surgery under general anesthesia are eligible for enter the research unless they have the following conditions: Acute and chronic uncontrolled illness,Drug addiction, history of taking anti-inflammatory drugs and corticosteroids, autoimmune diseases, history of drug and food allergy (especially egg products)

**Intervention groups**

In group A, the control group, is not given an intervention, and anesthetic dose of propofol (2 mg / kg) is injected one minute after administration of fentanyl (3mic / kg) and midazolam (0.15 mg / kg). In group B, propofol 50micg / kg / min is infused for one minute, then fentanyl and midazolam, and one minute later, the induction dose of propofol is injected. In group C, initially, infusion of propofol at a dose of 100mic / kg / min for one minute, then fentanyl and midazolam, and one minute later, the induction dose of propofol is injected.

**Main outcome variables**

Pain When Injecting Bolus Propofol Changes in serum level of complement factor C3

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20170301032837N2**
Registration date: **2017-12-03, 1396/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-03, 1396/09/12**
Update count: **0**

**Registration date**

2017-12-03, 1396/09/12

**Registrant information**

**Name**

Behrooz Zaman

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**
**Funding source**
The cost of conducting tests is initially paid by program administrators

**Expected recruitment start date**
2017-02-13, 1395/11/25
**Expected recruitment end date**
2018-02-14, 1396/11/25
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparative study of the effect of propofol infusion before injection of induction dose on injection induced pain and changes in serum complement in patients candidate for general anesthesia

**Public title**
The effect of infusion of propofol before it's induction dose on injection pain
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients are candidates for general anesthesia ASA I & II
**Exclusion criteria:**
uncontrolled chronic and acute diseases age >60 age<18 history of hypersensitivity to drugs and foods History of using NSAIDS and corticostroides opioid addiction
**Age**
From **18 years** old to **60 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this research, simple randomization method is used using sealed envelope. The patient chooses one of the three envelopes, in which the letters A, B, C are written, and is placed in one of the three groups.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
During the study, the patient is simply blind because of the lack of knowledge about how the anesthetic induction was performed.The laboratory, which is responsible for assessing the serum level of complementary C3 factor, is blind. The researcher is involved in the induction of anesthesia and intervention, and is not blind to the type of intervention and non-intervention.
**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**
Hemmat highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1449614535
**Approval date**
2017-02-12, 1395/11/24
**Ethics committee reference number**
IR.IUMS.REC 1395.9311174005

## Health conditions studied

### 1

**Description of health condition studied**
Pain caused by propofol injection
**ICD-10 code**
T41.1X5
**ICD-10 code description**
Adverse effect of intravenous anesthetics

## Primary outcomes

### 1

**Description**
Pain intensity
**Timepoint**
At the time of the intervention
**Method of measurement**
visual analogue scale of pain

## Secondary outcomes

### 1

**Description**
Changes in serum level of complement factor C3
**Timepoint**
Immediately before the intervention and two minutes after the intervention
**Method of measurement**
Blood sampling and laboratory measurements

## Intervention groups

### 1

**Description**
Control group: After IV catheterizationin the patient's hand, 5 cc blood samples are taken to measure the serum level of complement factor C3. One minute later fentanyl 3 micg/kg and midazolam 0.15 mg/kg is injected. One minute later, general anesthesia is induced with propofol 2 mg/kg and atracurium 0.5 mg/kg.One minute later, 5 cc blood sample are taken from the same hand and above the injection site to measure the serum level of factor C3.During injection of Bolus Propofol, pain intensity is assessed by VAS.
**Category**
Other

### 2

**Description**
Intervention group 1: After intravenous catheterization, 5 cc blood samples are taken to measure the serum level of complement factor C3.Then propofol infusion 50µg/kg/min ( Manufactured by: Fresenius Kabi Ausria GmbH A-8055 Graz , Austria ) is administered for one minute. Then fentanyl 3 µg/kg and midazolam 0.15 mg/kg are injected.One minute later, general anesthesia is induced with propofol 2 mg/kg and atracurium 0.5 mg/kg.One minute later, 5 cc blood sample are taken from the same hand and above the injection site to measure the serum level of factor C3.During injection of Bolus Propofol, pain intensity is assessed by VAS.
**Category**
Prevention

### 3

**Description**
Intervention group 2: After intravenous catheterization, 5 cc blood samples are taken to measure the serum level of complement factor C3.Then propofol infusion 100µg/kg/min ( Manufactured by: Fresenius Kabi Ausria GmbH A-8055 Graz , Austria ) is administered for one minute. Then fentanyl 3 µg/kg and midazolam 0.15 mg/kg are injected.One minute later, general anesthesia is induced with propofol 2 mg/kg and atracurium 0.5 mg/kg.One minute later, 5 cc blood sample are taken from the same hand and above the injection site to measure the serum level of factor C3.During injection of Bolus Propofol, pain intensity is assessed by VAS.
**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Firoozgar hospital
**Full name of responsible person**
Sara Parak
**Street address**
Firoozgar hospital, Behafarin St., Karim kan Ave., Valiasr Sq., Tehran
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
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**Full name of responsible person**
Dr. seyed ali javad moosavi
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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**
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**

Behrooz Zaman

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Position**

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**Web page address**

## 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**

Yes - There is a plan to make this available

**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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All information used for this research can be shared after unidentifying the identity of patients. Also, statistical information, information analysis, study method, findings and conclusions can be shared.

**When the data will become available and for how long**

Starting access after accepting by a valid scientific journal and publishing it

**To whom data/document is available**

For academic researchers and in the field of science

**Under which criteria data/document could be used**

All researchers can use all published material and if all or part of this research is published by other people, the name and source of this research and its researchers should be mentioned.

**From where data/document is obtainable**

Dr. Behrooz Zaman Email: zaman.b@iums.ac.ir

**What processes are involved for a request to access data/document**

The applicant can request the type of files by email.

**Comments**