Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 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)

Phone
+98 21 8871 7272
Email address
zaman.b@iums.ac.ir

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
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1600
Email
parak_s@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. seyed ali javad moosavi
Street address
hemmat highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
research.m@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

Behrooz Zaman

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Iran university of medical sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8871 7272

Fax

Email

zaman.b@iums.ac.ir

Web page address

Person responsible for scientific 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

Anesthesiology

Street address

Iran university of medical sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8871 7272

Fax

Email

zaman.b@iums.ac.ir

Web page address

Person responsible for updating data

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

Anesthesiology

Street address

Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8871 7272

Fax

Email

zaman.b@iums.ac.ir

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