Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of induction of anesthesia with etomidate and propofol on surgical stress responses in spinal elective surgery

Protocol summary

Study aim

Comparison between Induction of Anesthesia with Atomidate and Propofol on Surgical Stress Responses

Design

In this double-blind clinical trials study, 60 patients undergoing spinal surgery were randomly divided into three groups: the first intervention group (recipient of Atomidate) and the second group (recipient of Propofol) and control.

Settings and conduct

In this study, 60 patients who were candidates for spinal surgery in Golestan Hospital in Ahvaz were selected as available and were divided into three groups of first and second intervention and control in a simple random method. In the first intervention group, 0.3 mg/kg of atomidate and in the second intervention group, 2.2 mg / kg propolis was injected intravenously for induction. The control group also receives routine medications such as sodium thiopental 5 mg/kg. In order to conduct a two-way blind study, patients and researchers who take blood samples do not know which drug groups 1 and 2 and which group received the routine drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria include:Patients are candidates for spinal elective surgery, Lack of bacterial or viral infection, Lack of autoimmune diseases, connective tissue disease, peripheral vascular disease, liver and kidney disorders, heart failure, and mental disorders and Exclusion criteria include: dissatisfaction to continue participating in this study.

Intervention groups

In the first intervention group, 0.3 mg / kg of Atomidate and in the second intervention group, 2.2 mg / kg Propofol was injected intravenously for induction.The control group also receives routine medications such as 5 mg/kg sodium Thiopental.

Main outcome variables

Patients who entered the study, screened for serum IL-1 and IL-6 levels, albumin, glucose, Crp, and cortisone were measured immediately before surgery and anesthesia, 24 hours, 48 hours, and one week after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190506043492N5**
Registration date: **2020-07-07, 1399/04/17**
Registration timing: **retrospective**

Last update: **2020-07-07, 1399/04/17**
Update count: **0**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Milad Arabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

arabi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

2018-07-11, 1397/04/20

Actual recruitment end date

2020-03-10, 1398/12/20

Trial completion date

2020-03-14, 1398/12/24

Scientific title

Comparison of induction of anesthesia with etomidate and propofol on surgical stress responses in spinal elective surgery

Public title

Induction of anesthesia with etomidate and propofol on surgical stress responses

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Lack of severe bacterial or chronic viral infection Do not take antidepressants Lack of autoimmune diseases Lack of connective tissue disease Lack of liver and kidney disorders Lack of peripheral vascular disease, heart failure, thyroid disease Lack of mental disorders

Exclusion criteria:

Dissatisfaction with continuing to study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly selected and randomly divided into two groups (Atomidate receiver) and the second group (Propofol receiver) through random number tables, so that for the first group, individual numbers were used and for the second group, even numbers were used.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients were unaware that they were in the atomidate group or propofol, a person who took a blood sample to check for laboratory tests related to the patient's stress response, and a statistical analyzer who did not know the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357157941

Approval date

2019-10-30, 1398/08/08

Ethics committee reference number

IR.AJUMS.REC.1398.561

Health conditions studied

1

Description of health condition studied

Stress Rresponse

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

Primary outcomes

1

Description

Serum level IL-1

Timepoint

Immediately before surgery and anesthesia, 24 hours, 48 hours and one week after surgery

Method of measurement

IL-1 blood serum levels in a blood biochemistry test

2

Description

Serum level IL-2

Timepoint

Immediately before surgery and anesthesia, 24 hours, 48 hours and one week after surgery

Method of measurement

Blood serum IL-2 levels in a blood biochemistry test

3

Description

Serum albumin levels

Timepoint

Immediately before surgery and anesthesia, 24 hours, 48 hours and one week after surgery

Method of measurement
Serum levels of blood albumin in a blood biochemistry test

4

Description
Serum glucose levels
Timepoint
Immediately before surgery and anesthesia, 24 hours, 48 hours and one week after surgery
Method of measurement
Serum blood glucose levels in a blood biochemistry test

5

Description
C-reactive-protein (Crp) Level
Timepoint
Immediately before surgery and anesthesia, 24 hours, 48 hours and one week after surgery
Method of measurement
Serum Crp blood levels in blood biochemistry tests

6

Description
Serum cortisol levels
Timepoint
Immediately before surgery and anesthesia, 24 hours, 48 hours and one week after surgery
Method of measurement
Serum levels of blood cortisol in a blood biochemistry test

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group:In order to induce anesthesia, 0.3 mg / kg of atomidate (oxy-nac, Elixir Pharmaceuticals, Boroujerd, Iran) were injected intravenously.
Category
Prevention

2

Description
Second Intervention group: In order to induce anesthesia, 2.2 mg / kg of propofol (Oxy-Nak, Elixir Pharmacy, Boroujerd, Iran) was injected intravenously.
Category
Prevention

3

Description
Control group: In order to induce anesthesia, 5 mg / kg sodium thiopental (Oxy-Nak, Elixir Pharmacy, Boroujerd, Iran) was injected intravenously.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Mohamad Mahdi Mina
Street address
Golestan Hospital, Golestan Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Vice Chancellor For Research of Ahvaz Jundishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
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Mahdi552m@hotmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mohamad Mahdi Mina

Position

Associate Professor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Contact

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Full name of responsible person

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Position

Anesthesiologist

Latest degree

Specialist

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Person responsible for updating data

Contact

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Position

Associate Professor

Latest degree

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Other areas of specialty/work

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Email

Mahdi552m@hotmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available