Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Sufentanil and Midazolam for reduction of Myoclonic movements fallowing etomidate injection in candidate patients for ocular surgery

Protocol summary

Summary

Introduction: Etomidate as an intravenous anesthetic drug with minimal effects on respiratory and cardiovascular stability, but its side effects is pain on injection and Myoclonus. The aim of present study is to compare the effects of Sufentanil and Midazolam as premedication in reducing myoclonus induced by intravenously administration of Etomidate. Study design: in this randomized double blind trial, 40 adult patients with ASAII-III undergoing elective surgery and general anesthesia for elective ocular surgery are entered to study. Methods: patients undergoing fluid therapy before induction of 5 cc/kg within 10 minutes. Routine monitoring including pulse oximetry, ECG, NIBP and Capnography are done for patient. Intervention: patients were randomly assigned into two groups. The patients are divided into two groups according to a table of random numbers. First group is received Sufentanil 0.2 µ/Kg and the second group is received Midazolam 0.3 mg/kg. These drugs as premedication drugs are received 90 seconds before induction with 0.3 mg/kg Etomidate. Outcome and measurement: Incidence of myoclonus is done by a person who had no knowledge of the groups. Severity of myoclonus is measured by According to Myoclonus Rating Scale, between 0 and 3, including 0 (no myoclonus), 1 or mild (small movements of body parts such as fingers or wrist), 2 or moderate (gentle movements of two different muscle groups, such as face and feet, 3 or severe (severe clonic movements and muscle groups on two or more extremities or rapid induction). Then two groups are compared and significant differences in the incidence of myoclonus show the effect of these medicines.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307164780N2**
Registration date: **2013-07-25, 1392/05/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-25, 1392/05/03

Registrant information

Name
Mohammad Alipour
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 1801 2612
Email address
alipourm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research vice chancellor of Mashhad University of Medical Sciences

Expected recruitment start date

2011-09-09, 1390/06/18

Expected recruitment end date

2013-11-09, 1392/08/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Sufentanil and Midazolam for reduction of Myoclonic movements fallowing etomidate injection in candidate patients for ocular surgery

Public title
Effect of Sufentanil and Midazolam for reduction of Myoclonic movements
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criterion: adult patients ASAII-III who candidate for elective surgery. Exclusion criteria: patients with impaired adrenal function; sensitivity to drugs; mental disorders, neuromuscular disorders; seizures; and electrolyte abnormalities.
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Mashhad University of Medical Sciences
Street address
Research vice chancellor of Mashhad University of Medical Sciences, Daneshgah street
City
Mashhad
Postal code
Approval date
2011-07-09, 1390/04/18
Ethics committee reference number
89795

Health conditions studied

1

Description of health condition studied
Myoclonic movements
ICD-10 code
G25.3
ICD-10 code description
Drug-induced myoclonus

Primary outcomes

1

Description
Myoclonus severity
Timepoint
At the end of the study
Method of measurement
According to Myoclonus Rating Scale into mild, moderate and sever

Secondary outcomes

empty

Intervention groups

1

Description
First group is received sufentanil 0.2 µ/Kg
Category
Treatment - Drugs

2

Description
Second group is received midazolam 0.3 mg/kg.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Research vice chancellor of Mashhad University of medical sciences

Full name of responsible person

Dr. Tavakol Afshar

Street address

Research vice chancellor, Ghoreishy building, University street

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research vice chancellor of Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohammad Alipour

Position

Anesthesiologist

Other areas of specialty/work

Street address

Ghaem Hospital

City

Mashhad

Postal code

Phone

+98 51 1801 2612

Fax

Email

Alipourm@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohammad Alipour

Position

Anesthesiologist

Other areas of specialty/work

Street address

Ghaem Hospital

City

Mashhad

Postal code

Phone

+98 51 1801 2612

Fax

Email

Alipourm@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

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Dr Mohammad Alipour

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Street address

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+98 51 1801 2612

Fax

Email

Alipourm@mums.ac.ir

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