

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of Sufentanil and Midazolam for reduction of Myoclonic movements following 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 following 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 committee 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

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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