

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The comparison of the effect of pretreatment with low dose of midazolam, low dose of etomidate, remifentanyl and sulfate magnesium on reduction or prevention of myoclonus after etomidate induction in orthopedic surgery

Protocol summary

Summary

The purpose of this study is comparison of the effect of pretreatment with low dose of Midazolam, low dose of Etomidate, Remifentanyl, and Magnesium sulphate on reduction or prevention of Myoclonous (Some type of jerky movement of muscle) after Etomidate induction in orthopedic surgery. Inclusion criteria: ASA (American Society of Anesthesiologists) I, II; age between 18 to 59 years old. Exclusion criteria: patients with Neurological problems; allergy; those who have received sedative or analgesic drugs in the 24 hours ago. Patients in randomized blocks are divided into four groups: Midazolam (M) 0.015 mg/kg (M.S) 30 mg/kg, Magnesium sulphate 3 Remifentanyl (R) 1 mcg/kg Etomidate 0.03 mg/kg (E) intravenously. All drugs are injected intravenously. In the operation room, patients are monitored for standard electrocardiography, heart rate, pulse oximetry and non-invasive blood pressure. Induction of the anesthesia is the same way in all groups by using of 0.3 mg/kg etomidate intravenously After etomidate injection for 90 seconds, the presence and severity of myoclonus is checked. Assessment of myoclonus after injection of Etomidate is performed by another anesthesiologist who is blinded to the study procedure. Myoclonus is divided to 4 grades: 0: without myoclonus; 1: movement just in wrist; 2: movement in arm, elbow and shoulder and 3: movement in whole of the body.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070613456N1**

Registration date: **2014-08-14, 1393/05/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-08-14, 1393/05/23

Registrant information

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Abbas Sedighinejad

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of pretreatment with low dose of midazolam, low dose of etomidate, remifentanyl and sulfate magnesium on reduction or prevention of myoclonus after etomidate induction in orthopedic surgery

Public title

Reduction or prevention of Myoclonus after Etomidate infusion

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA (American Society of Anesthesiologists) I, II; age between 18 to 59 years old.
Exclusion criteria: patients with Neurological problems; allergy; those who have received sedative or analgesic drugs in the 24 hours ago.

Age

From **18 years** old to **59 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **284**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Guilan university of Medical Sciences

Street address

Namjoo street

City

Rasht

Postal code

4193893345

Approval date

2014-07-14, 1393/04/23

Ethics committee reference number

1930175710

Health conditions studied**1****Description of health condition studied**

Myoclonus

ICD-10 code

G25.3

ICD-10 code description

Drug-induced myoclonus

Primary outcomes**1****Description**

Myoclonus

Timepoint

Within 90 seconds after injection of Etomidate as the main drug for induction of anesthesia

Method of measurement

Myoclonus Grade

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention1: Injection of low dose of Midazolam 0.015mg/kg as a premed before Etomidate

Category

Prevention

2**Description**

Intervention 2: Injection of sulfate magnesium 30 mg/kg before induction of anesthesia with Etomidate

Category

Prevention

3**Description**

Intervention 3: Injection of Remifentanyl 1 micg/kg before Etomidate

Category

Prevention

4**Description**

Intervention 4: Injection of low dose of Etomidate 0.03 mg/kg before induction of anesthesia with Etomidate

Category

Prevention

Recruitment centers**1****Recruitment center**

Name of recruitment center

Poursina Hospital
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Person responsible for scientific inquiries

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Guilan University of
Medical Sciences
Full name of responsible person
Abtin Heidarzadeh
Street address
Shahid beheshti Highway
City
Rasht
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Vice chancellor for research of Guilan 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
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Person responsible for updating data

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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