Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 sulphate3 Remifentanyl (R)1 micg/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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Name of organization / entity
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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
Full name of responsible person
Abbas sedighinejad
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Rasht

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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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