

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effect of Diazepam and Etomidate on hemodynamic responses to laryngoscopy and intubation

#### Protocol summary

##### Summary

In this clinical trial we are aiming at comparing hemodynamic responses following laryngoscopy and intubation after induction of anesthesia with 0.4mg/kg Diazepam and 0.3mg/kg Etomidate. This is a double blind study on 180 patients undergoing elective orthopedic surgery with average length of 1.5 - 4 hours. Inclusion criteria are: American Association of Anesthesiologists' (ASA) classification of I or II; age 25 -65 years. Exclusion criteria are: ASA classification of 3-6 (severe systemic disorders such as CRF and CHF); patients with fever, anemia, seasonal or food allergy or known medicine hypersensitivity; hypertension; hypo tension; consumption of beta blockers; kidney and liver disorders; drug abuse; dehydration and anxious patients with heart rate of 100 b/m or more. The patients after obtaining informed consent will be divided into two groups of 90 ones. The method of anesthesia in both is similar consisting of Fentanyl (2µg/kg) as an analgesic, Succinyl 2mg/kg for relaxation and intubation, and Isoflurane, N2O and O2 for maintenance of anesthesia. However in group 1 we employ 0.4 mg/kg Diazepam and in group 2 we administer 0.3 mg/kg Etomidate. The hemodynamic conditions of the patients will be recorded in four steps (at the time of entrance, just after intubation, 5 and 10 minutes after intubation). Awareness of patients will be determined at the end as well. Collected data will be analyzed by means of SPSS.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013010512007N1**  
Registration date: **2013-01-26, 1391/11/07**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-01-26, 1391/11/07

##### Registrant information

###### Name

Mohammad Reza Doroudian

###### Name of organization / entity

Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 1246 2055

###### Email address

mdoroudian@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kerman University of Medical Sciences

##### Expected recruitment start date

2012-09-01, 1391/06/11

##### Expected recruitment end date

2013-03-01, 1391/12/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of Diazepam and Etomidate on hemodynamic responses to laryngoscopy and intubation

##### Public title

Comparison of the effect of Diazepam and Etomidate on cardiovascular system after laryngoscopy and intubation

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria are: American Association of Anesthesiologists' (ASA) classification of I or II; age 25-65 years. Exclusion criteria are: ASA classification of 3-6 (severe systemic disorders such as CRF and CHF); patients with fever, anemia, seasonal or food allergy or known medicine hypersensitivity; hypertension; hypotension; consumption of beta blockers; kidney and liver disorders; drug abuse; dehydration and anxious patients with heart rate of 100 b/m or more.

#### Age

From **25 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **180**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

The patients will be assessed in two identical groups of Diazepam and Etomidate. Randomization is made through minimization which neutralizes the issue of age. In fact these two groups have an identical range of age. The mechanism of collecting data is a checklist which is filled through inspection, examination and reviewing documents. The first part of it is about demographic information and the second part is for recording our observations which documents hemodynamic condition of the patient in four steps (after lying on surgical bed, immediately after intubation, 5 and 10 minutes later). We collect these data by means of digital monitoring device. At the end of anesthesia the awareness of patient will be assessed as well. We have to mention that the resident of anesthesia is not in participation of evaluating hemodynamic values and a technician will documents them without awareness of injected drug.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kerman University of Medical Sciences Ethics Committee

##### Street address

Jomhoori boulevard

#### City

Kerman

#### Postal code

#### Approval date

2011-12-11, 1390/09/20

#### Ethics committee reference number

k/90/306

## Health conditions studied

### 1

#### Description of health condition studied

intubation

#### ICD-10 code

T88.4

#### ICD-10 code description

Failed or difficult intubation

## Primary outcomes

### 1

#### Description

blood pressure

#### Timepoint

after lying on surgical bed, immediately after intubation, 5 and 10 minutes later

#### Method of measurement

digital monitoring device

### 2

#### Description

heart rate

#### Timepoint

after lying on surgical bed, immediately after intubation, 5 and 10 minutes later

#### Method of measurement

digital monitoring device

## Secondary outcomes

### 1

#### Description

awareness

#### Timepoint

at the end of anesthesia

#### Method of measurement

asking the patient

## Intervention groups

### 1

#### Description

Intervention: Diazepam (each ampoule contains 10mg/2ml, made by Kimidaroo/Iran) injecting IV with dosage of 0.4mg/kg before induction of anesthesia

#### Category

Treatment - Drugs

2

### Description

Control group: Etomidate (each ampoule contains 20mg/10ml, made by Janssen-Cling/Australia) injecting IV and stat with dosage of 0.3mg/kg before induction of anesthesia

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Bahonar Hospital of Kerman

#### Full name of responsible person

#### Street address

#### City

Kerman

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Deputy of Research Kerman University of Medical Sciences

#### Full name of responsible person

Fatemeh Hassani

#### Street address

Tahmasbabad Square, Ebnesina Street

#### City

Kerman

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Deputy of Research Kerman 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

Kerman University of Medical Sciences

#### Full name of responsible person

Mahdi Khodadadzadeh

#### Position

MD, Resident of anesthesiology

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

Mohammadreza Doroudian

#### Position

anesthesiologist

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Mahdi Khodadadzadeh

#### Position

Resident of anesthesiology

#### Other areas of specialty/work

#### Street address

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#### City

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#### Postal code

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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*