

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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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; 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.

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

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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