

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Post traumatic stress and awareness in traumatic lower limb surgery patients after neuraxial anesthesia : A randomized clinical trial

Protocol summary

Study aim

Comparison post traumatic stress and awareness in traumatic lower limb surgery patients after neuraxial anesthesia with propofol and midazolam drugs

Design

A double blind, parallel, randomized clinical trial with a parallel group design of 220 patients. randomization was performed with a random sequence with SAS software

Settings and conduct

double blind randomized clinical trial in bahonar hospital of Kerman city, patients were randomly assigned to one of the groups of study, to receive propofol or midazolam sedation during neuroaxial anesthesia. main investigator and data analyzer were masked of patients allocation. patients did not know which drug prescribed and checklists did not contain any drug name. only the nurse know the name of medication.

Participants/Inclusion and exclusion criteria

age between 18-50 years old trauma and were a candidate for lower extremity surgery,

Intervention groups

In propofol group, propofol infusion (at dose of 25-75 µg/kg/minute) was infused during surgery and in Midazolam group 1-2 mg of midazolam was injected PRN until patients reached a score of 3 according to Modified observers Assessment of Alertness/ sedation scale

Main outcome variables

stress level during neuraxial anesthesia in lower extremity surgery in trauma patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190819044559N3**

Registration date: **2020-06-13, 1399/03/24**

Registration timing: **retrospective**

Last update: **2020-06-13, 1399/03/24**

Update count: **0**

Registration date

2020-06-13, 1399/03/24

Registrant information

Name

Morteza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3223 5011

Email address

mortezahashemian@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-29, 1398/06/07

Expected recruitment end date

2020-02-26, 1398/12/07

Actual recruitment start date

2019-09-12, 1398/06/21

Actual recruitment end date

2020-03-14, 1398/12/24

Trial completion date

2020-04-02, 1399/01/14

Scientific title

Post traumatic stress and awareness in traumatic lower limb surgery patients after neuraxial anesthesia : A randomized clinical trial

Public title

Stress level after surgery in spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Trauma and candidate for lower extremity surgery Age between 18-50 years

Exclusion criteria:
History of psychiatric disorders Previous history of lower leg surgery Refusal to attend the study More than 3 hours of surgery duration Severe blood loss Decrease in consciousness and endotracheal intubation during surgery

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **220**
Actual sample size reached: **220**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients randomly divided in two groups (110 patients in each group) using random allocation sequence with SAS statistical software. according to this method a simple randomization list product and patients` involvement in each group determine base on order entry. we used sequentially numbered, sealed opaque envelopes for allocation concealment. patients (individuals) were the randomization units.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients, main investigator and data analyser were masked of patients allocation. patients did not know which drug prescribed and checklists did not contain any drug name. only the nurse know the name of medication.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Vice chancellor for research, Kerman University of

Medical Sciences, Ebn-e-Sina St.,Jahad Blvd, Kernan,Iran

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2016-02-13, 1394/11/24

Ethics committee reference number

.kmu.REC.1394.508

Health conditions studied

1

Description of health condition studied

Post-traumatic stress

ICD-10 code

F43.11

ICD-10 code description

Post-traumatic stress disorder, acute

Primary outcomes

1

Description

Stress level after trauma according to Mississippi questionnaire

Timepoint

One day before surgery, after transfer to Recovery,1 and 7 days after surgery

Method of measurement

Mississippi questionnaire

2

Description

Awareness level after neuraxial anesthesia with midazolam or propofol

Timepoint

One day before surgery, after transfer to Recovery,1 and 7 days after surgery

Method of measurement

The Brace questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Propofol infusion of 25-75 micro grams per kilogram per minute is recommended

Category

Treatment - Drugs

2

Description

Control group: 1-2 mg of midazolam PRN is recommended

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid bahonar hospital

Full name of responsible person

Morteza Hashemian

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Gharani street, Kerman, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Morteza Hashemian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Fax

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available