

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Aug 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

**Street address**

Gharani street, Kerman, Iran

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**Postal code**

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mortezahashemian@kmu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr Abbas Pardakhti

**Street address**

Ebn-e-Sina St.,Jahad Blvd, Vice chancellor for research

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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

**Street address**

Gharani st. Shahid Bahonar hospital

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

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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