

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Comparison of catheter-related bladder discomfort in the two methods of Haloperidol and Ketamine with Haloperidol and Pethidine in male patients after elective lumbar spine Laminectomy

#### Protocol summary

##### Study aim

Comparison of efficacy of two methods haloperidol and ketamine with haloperidol and pethidine in comparison with control group in which the patients receive normal saline as placebo, on catheter related bladder discomfort (CRBD)

##### Design

A clinical trial with a community-based and pragmatic control group, with parallel groups, triple-blind, randomized. 119 male patients with laminectomy were divided into 3 groups: 1: 0.04 mg/kg haloperidol and 0.5 mg/kg ketamine in 5cc distilled water, 2: 0.04 mg/kg haloperidol and 0.5 mg/kg pethidine in 5 cc distilled water, intervention 3: In normal saline control group, they are randomly divided into placebo. Randomization method and description of each method: Simple randomization, randomization unit: Individual, randomization tool: random number table, clinical trial phase 2.

##### Settings and conduct

The main aim of the study is comparison of catheter-related bladder discomfort in the two methods of Haloperidol and Ketamine with Haloperidol and Pethidine in male patients after elective lumbar spine Laminectomy. This double blinded randomized phase 2 clinical trial was done in Sina hospital of Tehran city. 119 male patients with laminectomy were divided into 3 groups: 1: 0.04 mg/kg haloperidol and 0.5 mg/kg ketamine in 5cc distilled water, 2: 0.04 mg/kg haloperidol and 0.5 mg/kg pethidine in 5 cc distilled water, intervention 3: In normal saline control group, they are randomly divided into placebo. Randomization method and description of each method: Simple randomization, randomization unit: Individual, randomization tool: random number table, clinical trial phase 2. In this study, the patients, measuring the outcomes of study participants (researchers) or Data Monitoring Committee

(analyzers) of the patients unaware about intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA class I and II, Male gender, Age between 18 and 70 years. Exclusion criteria: Inability to extubate patients after surgery, history of urological surgery, patients who have any damage or distracting pain other than the site of surgery, patients with any lesion and central nervous system disease; patients with a history of chronic pain; patients with severe heart and liver disease or evidence of long QT segment in electrocardiography.

##### Intervention groups

Intervention 1: 0.04 mg/kg haloperidol and 0.5 mg/kg ketamine Intervention 2: 0.04 mg/kg haloperidol and 0.5 mg/kg pethidine Intervention 3: Normal saline as placebo

##### Main outcome variables

Bladder discomfort associated with, pain and sedation.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171012036730N2**

Registration date: **2018-02-25, 1396/12/06**

Registration timing: **retrospective**

Last update: **2018-02-25, 1396/12/06**

Update count: **0**

##### Registration date

2018-02-25, 1396/12/06

##### Registrant information

##### Name

Nazafarin Kamalzadeh

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
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| <b>Phone</b><br>+98 21 6634 8545                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Phase</b><br>3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Email address</b><br>nkamalzadeh@razi.tums.ac.ir                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Groups that have been masked</b><br><ul style="list-style-type: none"> <li>• Participant</li> <li>• Care provider</li> <li>• Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Recruitment status</b><br><b>Recruitment complete</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Funding source</b><br>Tehran University of Medical Sciences                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Sample size</b><br>Target sample size: <b>119</b><br>Actual sample size reached: <b>119</b>                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Expected recruitment start date</b><br>2016-09-22, 1395/07/01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Expected recruitment end date</b><br>2017-09-23, 1396/07/01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Randomization description</b><br>Randomization method: Simple randomization, randomization unit: individual, randomization tool: random number table                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Actual recruitment start date</b><br>2016-09-22, 1395/07/01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Blinding (investigator's opinion)</b><br>Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Actual recruitment end date</b><br>2017-09-23, 1396/07/01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Blinding description</b><br>In this study, the patients, measuring the outcomes of study participants (researchers) or Data Monitoring Committee (analyzers) of the patients unaware about intervention.                                                                                                                                                                                                                                                                                                                              |
| <b>Trial completion date</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Placebo</b><br>Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Scientific title</b><br>Comparison of catheter-related bladder discomfort in the two methods of Haloperidol and Ketamine with Haloperidol and Pethidine in male patients after elective lumbar spine Laminectomy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Assignment</b><br>Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Public title</b><br>Effect of ketamine and haloperidol with pethidine and haloperidol for prevention of catheter-related bladder discomfort                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Other design features</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Purpose</b><br>Prevention                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Secondary Ids</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Inclusion/Exclusion criteria</b><br><b>Inclusion criteria:</b><br>Age between 18 and 70 years Male gender American Society of Anesthesiologists (ASA) physical status classification I, II<br><b>Exclusion criteria:</b><br>Inability of extubating the patients after surgery Any history of urological surgery Patients who have any damage or distracting pain other than the site of surgery Patients with any lesion and central nervous system disease History of chronic pain History of opioids or other substances consumption chronically Benign Prostatic Hyperplasia or any urinary system obstruction Urinary tract infection or urinary tract stone Severe heart and liver disease or evidence of long QT segment in electrocardiography History of overactive bladder (need to urinate more than 3 times during sleep or more than 8 times a day) Obesity (body mass index more than 40 kilogram per square meter) Dementia or any disorder which leads to inappropriate orientation and inability to communicate verbally End stage renal disease (urinary volume less than 500cc per 24 hours) Proved mental illness Any apparent bladder dysfunction due to lumbar spinal cord stenosis Sensitivity to phenylephrine, ketamine or pethidine History of monoamine oxidase inhibitor (MAOI) usage in the recent two weeks | <b>Ethics committees</b><br><br><b>1</b><br><b>Ethics committee</b><br><b>Name of ethics committee</b><br>Ethics Committee of Tehran University of Medical Sciences<br><b>Street address</b><br>Research and Technology Department, 6th floor, Central Organization of the University, Ghods street, Keshavarz boulevard<br><b>City</b><br>Tehran<br><b>Province</b><br>Tehran<br><b>Postal code</b><br>141765361<br><b>Approval date</b><br>2016-06-07, 1395/03/18<br><b>Ethics committee reference number</b><br>IR.TUMS.REC.1395.2658 |
| <b>Age</b><br>From <b>18 years</b> old to <b>70 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Health conditions studied</b><br><br><b>1</b><br><b>Description of health condition studied</b><br>Catheter related bladder discomfort                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Gender</b><br>Male                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

**ICD-10 code**

Y84.6

**ICD-10 code description**

Urinary catheterization as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

**Primary outcomes****1****Description**

Catheter Related Bladder Discomfort severity

**Timepoint**

0, 1, 6, 24 hours after surgery

**Method of measurement**

based on asking patients based on Likert scale

**2****Description**

Pain

**Timepoint**

0, 1, 6, 24 hours after surgery

**Method of measurement**

Visual Analogue Scale (VAS)

**3****Description**

Sedation

**Timepoint**

0, 1, 6, 24 hours after surgery

**Method of measurement**

Richmond Sedation Score (RSS)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention 1: 0.04 mg/kg haloperidol and 0.5 mg/kg ketamine

**Category**

Treatment - Drugs

**2****Description**

Intervention 2: 0.04 mg/kg haloperidol and 0.5 mg/kg pethidine

**Category**

Treatment - Drugs

**3****Description**

Intervention 3: Normal saline as placebo

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Sina Educational, Research and Therapeutic Center

**Full name of responsible person**

Nazafarin Kamalzadeh

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Sina hospital, Hassan Abad square, Imam Khomei street, Tehran, Iran

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Sina hospital Research Center, Tehran 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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Nazafarin Kamalzadeh  
**Position**  
Resident  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Confidentiality of information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Journals

### When the data will become available and for how long

Start the access period from April, 2018

### To whom data/document is available

Researchers working in academia, science and industry

### Under which criteria data/document could be used

To be used clinically and post-correspondence with the authors

### From where data/document is obtainable

By correspondence or on-line visit to the Sina Hospital's Anesthesiology Department

### What processes are involved for a request to access

**data/document**

Review by the authors and the Ethics Committee of

Tehran University of Medical Sciences

**Comments**