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

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Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2016-09-22, 1395/07/01
Expected recruitment end date
2017-09-23, 1396/07/01
Actual recruitment start date
2016-09-22, 1395/07/01
Actual recruitment end date
2017-09-23, 1396/07/01
Trial completion date
empty

Scientific title
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

Public title
Effect of ketamine and haloperidol with pethidine and haloperidol for prevention of catheter-related bladder discomfort
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 70 years Male gender American Society of Anesthesiologists (ASA) physical status classification I, II
Exclusion criteria:
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
Age
From **18 years** old to **70 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **119**
Actual sample size reached: **119**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Simple randomization, randomization unit: individual, randomization tool: random number table
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the patients, measuring the outcomes of study participants (researchers) or Data Monitoring Committee (analyzers) of the patients unaware about intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Research and Technology Department, 6th floor, Central Organization of the University, Ghods street, Keshavarz boulevard
City
Tehran
Province
Tehran
Postal code
141765361
Approval date
2016-06-07, 1395/03/18
Ethics committee reference number
IR.TUMS.REC.1395.2658

Health conditions studied

1

Description of health condition studied
Catheter related bladder discomfort

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
Street address
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
Mohammad Reza Khajavi
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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

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Mohammad Reza Khajavi

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Professor

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Web page address

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