Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Comparative study of hemodynamic and renal effects of Pethidine and Marcaine during and after the operation in patients undergoing TUL surgery: double-blind randomized controlled clinical trial

Protocol summary

Study aim

Comparative study of hemodynamic and renal effects of Pethidine and Marcaine during and after the operation in patients undergoing TUL surgery: double-blind randomized controlled clinical trial

Design

This is a randomized clinical trial with a parallel design and a control group. This study is double-blinded that the drugs can be identified only through the serial insert on the container containing it. This study randomized, phase 2-3 will be performed on 66 patients. For randomization, a simple random method is used and participants are assigned to two intervention groups.

Settings and conduct

This study, which will be performed in Imam Reza Hospital in Kermanshah, is a double-blinded one. Participants and clinical caregivers will be kept blind in this study. Half an hour before the operation, a separate intravenous route is taken for all patients, and in case of increased blood pressure and heart rate due to anxiety and stress, 1000-500 cc of Ringer serum of 1 mg midazolam is infused.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidates for TUL surgery by their doctor; Patients who are in ASA class 1 and 2; Exclusion criteria: Patients with chronic diseases including heart disease and hypertension and advanced lung and neurological diseases;Patients taking opium;Patients who are contraindications to the spinal procedure

Intervention groups

The first intervention group will receive 15-15.5 mg of Markain 0.5% in the intervertebral space L3-L4 for spinal anesthesia by injection. The second intervention group will receive 1 mg of Pethidine in the L3-L4 intervertebral space for spinal anesthesia by injection.

Main outcome variables

Changes in blood pressure, changes in heart rate, urinary retention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N165**
Registration date: **2021-04-05, 1400/01/16**
Registration timing: **prospective**

Last update: **2021-04-05, 1400/01/16**
Update count: **0**

Registration date

2021-04-05, 1400/01/16

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-18, 1400/01/29

Expected recruitment end date

2021-07-20, 1400/04/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of hemodynamic and renal effects of Pethidine and Marcaine during and after the operation in patients undergoing TUL surgery: double-blind randomized controlled clinical trial

Public title
Comparative study of hemodynamic and renal effects of Pethidine and Marcaine during and after surgery in patients undergoing ureteral stone surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for TUL surgery by their doctor Patients who are in ASA class 1 and 2
Exclusion criteria:
Patients with chronic diseases including heart disease and hypertension and advanced lung and neurological diseases Patients taking opium Patients who are contraindications to the spinal procedure
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done in a simple random method, after identifying eligible patients, they will be randomly assigned a three-digit dedicated code. The last digit on the right determines the patient group. If this number is 0, 1, 2, 3, 4, it will be assigned in the first intervention group, and if this number is 5, 6, 7, 8, 9, it will be assigned in the second intervention group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Medications can only be identified by the serial number on the container. The serials are with the main researcher and will remain confidential until the end of the study. The charge of injecting medications will not know about the assignment of individuals to groups. The person evaluating the patients will also not know about the assignment. Therefore, this study will be a double-blinded one.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2021-02-16, 1399/11/28
Ethics committee reference number
IR.KUMS.REC.1399.1170

Health conditions studied

1

Description of health condition studied
Urological services with urine virtual stone
ICD-10 code
N21
ICD-10 code description
Calculus of lower urinary tract

Primary outcomes

1

Description
Blood pressure changes
Timepoint
Every 5 minutes until the end of the first 30 minutes, then every 15 minutes until the end of surgery and in the recovery room every 15 minutes until the recovery criteria are met.
Method of measurement
Using a pressure gauge

2

Description
Heart rate changes
Timepoint
Every 5 minutes until the end of the first 30 minutes, then every 15 minutes until the end of surgery and in the

recovery room every 15 minutes until the recovery criteria are met.

Method of measurement

Using a pulse oximeter

3

Description

Urinary retention

Timepoint

Before and after anesthesia

Method of measurement

Based on questions from the patient and based on observation and clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive 15-15.5 mg of Markain 0.5% in the intervertebral space L3-L4 for spinal anesthesia by injection.

Category

Treatment - Drugs

2

Description

The second intervention group will receive 1 mg of Pethidine in the L3-L4 intervertebral space for spinal anesthesia by injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Bahar Khodayar

Street address

Emam Reza Hospital, Parastar Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Bahar Khodayar

Position

Resident of anesthesia

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Javad Amini Saman

Position
Faculty member of Kermanshah University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Position
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Anesthesiology

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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
There is no more information

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

Statistical Analysis Plan
Not applicable

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
Not applicable

Data Dictionary
Not applicable