

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 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)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

##### 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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Email**

Baharkhodayar@yahoo.com

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

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Reza Khodarahmi

**Street address**

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

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rkhodarahmi@kums.ac.ir

**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**

Anesthesiology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**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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**Email**

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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