

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluation of postoperative analgesic effect of Intra muscular injection of methadon after induction of anesthesia in Renal Transplantation Surgery.

#### Protocol summary

##### Study aim

Determining the effect of intramuscular methadone injection on pain relief after kidney transplant surgery in recovery and ward

##### Design

A double-blind randomized clinical trial with control group, and parallel groups, phase 3-2 on 35 patients. Excel software was used to randomize.

##### Settings and conduct

A double blind clinical trial study on renal failure patients was performed at Sinai Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients with renal failure candidate for kidney transplant surgery aged 20-55 years old.

Exclusion criteria: history of drugs addiction, methadone use; neurological or psychiatric drugs; asthma, seizure and prolonged QT interval in EKG.

##### Intervention groups

Intervention group: after induction of anesthesia, 5 mg of methadone is injected intramuscularly with a 2 cc syringe. At the end of anesthesia, all patients received 1 gram of intravenous acetaminophen and after endotracheal extubation, pain intensity and agitation of patients in recovery and in the ward at 6, 12, 18 and 24 hours after entering the ward are evaluated. The total amount of analgesic requirement are evaluated during 24 hours after surgery. Control group: They received morphine 5 mg intramuscularly with a 2 cc syringe. At the end of anesthesia, all patients received 1 gram of intravenous acetaminophen and after endotracheal extubation, pain intensity and agitation of patients in recovery and in the ward at 6, 12, 18 and 24 hours after entering the ward are evaluated. The total amount of analgesic requirement are evaluated during 24 hours after surgery.

##### Main outcome variables

Incidence and severity of pain and agitation after kidney transplant surgeries

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130304012695N9**

Registration date: **2021-04-30, 1400/02/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-30, 1400/02/10**

Update count: **0**

##### Registration date

2021-04-30, 1400/02/10

##### Registrant information

##### Name

mohammadreza khajavi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6312 1220

##### Email address

khajavim@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-30, 1400/02/10

##### Expected recruitment end date

2022-02-19, 1400/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of postoperative analgesic effect of Intra muscular injection of methadon after induction of anesthesia in Renal Transplantation Surgery.

#### Public title

Reduction of pain of renal transplantation surgeries

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Renal failure candidate for renal transplant

##### Exclusion criteria:

History of drug addiction and methadone use  
History of neural or psychiatric drugs  
History of asthma or seizure  
Prolonged QT interval in EKG

#### Age

From **20 years** old to **55 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **70**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

To randomize patients with inclusion criteria, block balanced randomization is used. Before studying, one of the person who is not a member of the research team performs the randomization process by using Random generator software, forms four blocks for the intervention and control group. The complete cards of the four blocks are given to the head of the operating room, who is unaware of the study, in an envelope. A card is given to the patient after patient entrance to operating room.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

Participants: since patients are not aware of the type of study drug at the time of anesthesia induction they were blind about the group to which they were allocated. Those who evaluate the outcome: the assistant who records the results in this study does not know the type of group. Data collection officials: the person who analyzes the data also does not know the type of participating groups.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of the School of Medicine, Tehran  
University of Medical Sciences

##### Street address

Sina hospital, Hasan Abad Sq., Emam Khomeni st.

##### City

Tehran

##### Province

Tehran

##### Postal code

1136746911

#### Approval date

2021-04-21, 1400/02/01

#### Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1400.013

## Health conditions studied

### 1

#### Description of health condition studied

Abdominal Acute Pain after renal transplant surgery

#### ICD-10 code

R10.0

#### ICD-10 code description

Acute abdomen

### 2

#### Description of health condition studied

Postoperative stress and agitation

#### ICD-10 code

F43.0

#### ICD-10 code description

Acute stress reaction

## Primary outcomes

### 1

#### Description

Incidence and severity of abdominal pain

#### Timepoint

post extubation in recovery and 6,12,18 and 24 hours  
after surgery in ward

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Severity of postoperative agitation

#### Timepoint

Ramsy sedation Scale

#### Method of measurement

Post extubation in recovery and 6,12,18 and 24 hours  
after surgery in ward

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: after induction of anesthesia 5mg methadone intramuscularly was injected .After extubation, incidence and severity of abdominal pain and degree of agitation and total amount of analgesic consumption in in recovery and ward and 24 hours after surgery are evaluated

#### Category

Treatment - Devices

### 2

#### Description

Control group: after induction of anesthesia 5mg morphine intramuscularly was injected .After extubation, incidence and severity of abdominal pain and degree of agitation and total amount of analgesic consumption in in recovery and ward and 24 hours after surgery are evaluated

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sina Hospital

##### Full name of responsible person

Mohammad Reza Khajavi

##### Street address

Sina Hospital Imam khomeini st

##### City

Tehran

##### Province

Tehran

##### Postal code

1136746911

##### Phone

+98 21 6634 8550

##### Email

khajavim@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Sahraeian

##### Street address

Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

##### Phone

+98 21 8163 3685

##### Email

vcr@tums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

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

Mohammadreza Khajavi

##### Position

Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Sina Hospital Imam Khomeini

##### City

Tehran

##### Province

Tehran

##### Postal code

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##### Phone

+98 21 6312 1220

##### Fax

+98 21 6312 0000

##### Email

khajavim@tums.ac.ir

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammadreza Khajavi

**Position**

Professor

**Latest degree**

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**Other areas of specialty/work**

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is 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**

Yes - There is a plan to make this available

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

All information used for this research can be shared after unidentified the identity of patients. Also, statistical information, information analysis, study method, findings and conclusions can be shared.

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

Starting access after accepting by a valid scientific journal and publishing it

**To whom data/document is available**

For academic researchers and in the field of science

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

All researchers can use all published material and if all or part of this research is published by other people, the name and source of this research and its researchers should be mentioned.

**From where data/document is obtainable**

Mohammad Reza Khajavi

**What processes are involved for a request to access data/document**

The applicant can request the type of files by email. khajavim@tums.ac.ir

**Comments**

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammadreza Khajavi

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