

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison effect of local subcutaneous tramadol and methadone in post laparotomy pain control

#### Protocol summary

##### Study aim

Comparison effect of local subcutaneous tramadol and methadone in post laparotomy pain control

##### Design

A total of 60 patients were selected according to entry and exit criteria and the patients were randomly assigned to one of two groups of 30.

##### Settings and conduct

After patients selection, they will be randomly allocated to tramadol or methadone groups. Before scrubbing the skin and after closing the fascia, 100 mg tramadol in 10 cc normal saline or 70 µg/kg methadone in 10 cc normal saline will be injected around the wound. The severity of pain in patients 1, 6, 12, 18 and 24 hours after laparotomy was assessed using Visual analogue scales and noun phrases criteria.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing elective laparotomy with general anesthesia, Patients who do not have Epidural catheter, received no analgesics 6 hours prior to surgery. Exclusion criteria: Pregnancy, Diabetes or chronic kidney, liver or heart disease, previous laparotomy, opium addiction, psychological disease or chronic pain disorders.

##### Intervention groups

In tramadol group, 100 mg diluted tramadol and in methadone group, 70 microgram per kg methadone diluted in 10 cc normal saline, will be injected around the wound.

##### Main outcome variables

Intensity of pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120605009948N3**

Registration date: **2018-09-19, 1397/06/28**

Registration timing: **retrospective**

Last update: **2018-09-19, 1397/06/28**

Update count: **0**

##### Registration date

2018-09-19, 1397/06/28

##### Registrant information

###### Name

Majid Montazer

###### Name of organization / entity

Tabriz University of Medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3337 8435

###### Email address

montazerma@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-11-21, 1395/09/01

##### Expected recruitment end date

2017-11-22, 1396/09/01

##### Actual recruitment start date

2016-11-21, 1395/09/01

##### Actual recruitment end date

2017-11-22, 1396/09/01

##### Trial completion date

2018-05-21, 1397/02/31

##### Scientific title

Comparison effect of local subcutaneous tramadol and methadone in post laparotomy pain control

##### Public title

subcutaneous tramadol and methadone in post laparotomy pain control

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

• Patients who are electively underwent laparotomy. • Patients undergoing general anesthesia. • Patients with no Epidural catheter. • Do not use analgesic at least 6 hours before surgery

### Exclusion criteria:

Pregnancy Having Diabetes mellitus or chronic renal, liver or heart disease Previous laparotomy Opium addiction Chronic psychological disease Chronic pain disorders

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

Actual sample size reached: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The patients are simply randomized to two experimental groups (methadone or Tramadol) through random number table; received a special code and are treated with own group treatment.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University of Medical Sciences

##### Street address

Tabriz daneshgah av., Tabriz University of Medical Sciences. anesthesiology department

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

۱۴۷۶۶-۰۱۶۶۶

#### Approval date

2018-06-24, 1397/04/03

## Ethics committee reference number

IR.TBZMED.REC.1397.088

## Health conditions studied

### 1

#### Description of health condition studied

Upper abdominal laparotomy

#### ICD-10 code

S30

#### ICD-10 code description

Superficial injury of abdomen, lower back, pelvis and external genitals

## Primary outcomes

### 1

#### Description

Intensity of pain

#### Timepoint

1 hours after surgery, 6 hours after surgery, 12 hours after surgery, 18 hours after surgery and 24 hours after surgery

#### Method of measurement

Using VAS and NPS criteria

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Tramadol (100 mg of tramadol diluted with normal saline to 10 cc)

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Methadone (Methadone at a dose of 70 µg / kg diluted with normal saline to 10 cc)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz Imam Reza Hospital

##### Full name of responsible person

Mostafa Hojaty

##### Street address

Tabriz University of medical science

##### City

tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
1476651666  
**Phone**  
+98 41 3334 1994  
**Email**  
montazer55@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Majid Montazer Bavi Oliaii M.D  
**Street address**  
Thorax ward, Imam Reza Hospital, Tabriz Tabriz  
**City**  
tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
1476651666  
**Phone**  
+98 41 3334 7054  
**Email**  
montazer55@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tabriz 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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Mostafa Hojaty  
**Position**  
Resident of General Surgery  
**Latest degree**  
Specialist  
**Other areas of specialty/work**

General Surgery  
**Street address**  
Golgasht Ave.,  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5166614766  
**Phone**  
+98 41 3334 1994  
**Email**  
hojatmo@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Majid Montazer Bavi Oliaii M.D  
**Position**  
General Toracic Subspeciality,Assistant Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
Golgasht Ave.,  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
1476651666  
**Phone**  
+98 41 3334 7054  
**Email**  
montazer55@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Majid Montazer Bavi Oliaii M.D  
**Position**  
General Toracic Subspeciality  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
Golgasht Ave.,  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
1476651666

**Phone**

+98 41 3334 7054

**Email**

montazer55@yahoo.com

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

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

**Study Protocol**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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**

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