

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

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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

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Sponsors / Funding sources

1

Sponsor

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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
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

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Person responsible for updating data

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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