

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Comparison of analgesic effects of paracetamol and morphine infusion after elective laparotomy surgeries

#### Protocol summary

##### Summary

This is a double blind randomized trial to evaluate effects of intravenous paracetamol on postoperative pain control. Inclusion criteria are ASA I,II patients, age between 20 to 50 years old, elective laparotomy surgeries not more than 3h, without any history of opium addiction, prolonged analgesic or sedative consumption, cardiac, pulmonary, thyroid or hepatic dysfunction, and allergy to morphine and paracetamol. Exclusion criteria are serious disgusting complications such as nausea, vomiting or itching, no patient satisfaction of analgesic protocol and need to inject analgesic more than usual or severe hepatic or respiratory complications. Total sample size is 112. The trial intervention considered is intravenous infusion of morphine and paracetamol for postoperative pain management and the pain after surgery will be measured in different times. Nausea, vomiting and itching are secondary outcomes. Recruitment duration time is about 18 months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201203114969N6**

Registration date: **2012-04-09, 1391/01/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-04-09, 1391/01/21

##### Registrant information

##### Name

Alireza Pournajafian

##### Name of organization / entity

Tehran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8894 6762

##### Email address

drpournajafian@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Science

##### Expected recruitment start date

2010-09-23, 1389/07/01

##### Expected recruitment end date

2012-03-19, 1390/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of analgesic effects of paracetamol and morphine infusion after elective laparotomy surgeries

##### Public title

Comparison of analgesic effects of paracetamol and morphine infusion after elective laparotomy surgeries

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1- ASA I,II patients, 2- age between 20 to 50 years old, 3- elective laparotomy surgeries, 4- duration of surgery less than 3h, 5- no opium addiction, 6- no history of prolonged analgesic or sedative consumption, 7- no history of cardiac or pulmonary disease, 8- no thyroid or hepatic dysfunction, 9- no history of allergy to morphine and paracetamol. Exclusion criteria: 1- serious disgusting complications such as nausea, vomiting or itching, 2- no patient satisfaction of analgesic protocol

and need to inject analgesic more than usual, 3- severe hepatic or respiratory complications.

#### **Age**

From **20 years** old to **50 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **112**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Tehran University of Medical Science

##### **Street address**

Ghods st., Keshavarz blvd.

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2010-05-31, 1389/03/10

#### **Ethics committee reference number**

225

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Postoperative pain

#### **ICD-10 code**

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#### **ICD-10 code description**

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## **Primary outcomes**

### 1

#### **Description**

Postoperative pain

#### **Timepoint**

2, 4, 6, 12 and 24 hours after surgery

#### **Method of measurement**

Visual Analog Scale from 1 to 10

## **Secondary outcomes**

### 1

#### **Description**

Itching

#### **Timepoint**

During 24 hours after surgery

#### **Method of measurement**

Medical records and asking the patients

### 2

#### **Description**

Nausea and vomiting

#### **Timepoint**

During 24hours after surgery

#### **Method of measurement**

Medical records and asking the patients

## **Intervention groups**

### 1

#### **Description**

Intravenous infusion of 20 mg morphin during 24 hours after surgery

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intravenous infusion of 4 gr paracetamol during 24 hours after surgery

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Firoozgar Hospital

##### **Full name of responsible person**

Alireza Pournajafian

##### **Street address**

Beh Afarin st., karim khan blvd.

##### **City**

Tehran

## **Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Science

**Full name of responsible person**

Shohreh Asadi

**Street address**

Ghods st.,Kkeshavarz blvd.

**City**

Tehran

**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 Science

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Science

**Full name of responsible person**

Alireza Pournajafian

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

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**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical science

**Full name of responsible person**

Alireza Pournajafian

**Position**

Assistant professor

**Other areas of specialty/work**

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+98 21 8894 2622

**Email**

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**Web page address**

**Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*