

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

ICD-10 code description

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

Firoozgar Hospital, Beh Afarin st., karim khan blvd

City

Tehran

Postal code

1593748711

Phone

+98 21 8894 6762

Fax

+98 21 8894 2622

Email

a-Pournajafian@tums.ac.ir alipn78@yahoo.com

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

Street address

Firoozgar Hospital, Beh Afarin st., karim khan blvd

City

Tehran

Postal code

1593748711

Phone

+98 21 8894 6762

Fax

+98 21 8894 2622

Email

a-pournajafian@tums.ac.ir alipn78@yahoo.com

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