

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of patient-controlled analgesia with morphine and target-controlled analgesia with sufentanil in controlling post-operative pain

Protocol summary

Summary

40 patients 18-60 years old after major surgical operation (laparotomy, vertebral column operation, head and neck surgeries, pelvic operation, femoral operation) randomly will be allocated in one of two groups: PCA with morphine and TCI with sufentanil. The patients should be awake and no artificial ventilation needed. In the first group, patients will receive morphine sulphate with PCA pump 1 mg IV as bolus dose, then 1 mg/hour as continuous dose and 1 mg when patients demand (with lock out time of 20 min), in second group after operation, patients will receive sufentanil as analgesic with TCI pump with brain target concentration of 0.2 ng/ml. The goal of analgesic administration is to keep visual analogue scale(VAS) less than 3. VAS will be measured and recorded every 2 hour. If VAS>3, the continuous dose of morphine will be increased to 2 mg/h in the first group and the target brain concentration will be increased to 0.3 in second group. The mean of VAS in 24h after operation in two groups will be compared. Side effects such as nausea and vomiting, pruritus, depressed ventilation, decreased consciousness and vital signs will be compared between two groups. Ease of use of pump by personnel and patients satisfaction will also be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138707271361N1**

Registration date: **2009-01-04, 1387/10/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-01-04, 1387/10/15

Registrant information

Name

Naser Yeganeh

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

4276309 831 98+

Email address

nyeganeh@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Pro-Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

Expected recruitment start date

2008-12-30, 1387/10/10

Expected recruitment end date

2009-06-30, 1388/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of patient-controlled analgesia with morphine and target-controlled analgesia with sufentanil in controlling post-operative pain

Public title

Comparison of two methods of analgesia after major surgical operations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having been carried out a major

surgical operation, Being awake in postoperative period, Age 18-60, Exclusion criteria: Denial of patients, Depressed consciousness, Need for mechanical ventilation after operation, Dependence to opium or other sedatives like Benzodiazepines.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences ethical committee

Street address

Kermanshah University of Medical Sciences, Pro-Vice-Chancellor for Research

City

Kermanshah

Postal code

Approval date

2008-05-18, 1387/02/29

Ethics committee reference number

87021

Health conditions studied

1

Description of health condition studied

Post operative analgesia

ICD-10 code

Y45.o

ICD-10 code description

complication of medical and surgical care-opioids and related analgesics

Primary outcomes

1

Description

Pain

Timepoint

every 2 hours until 24 hours after surgery

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Nausea and Vomiting

Timepoint

every 2 hours until 24 hours after operation

Method of measurement

observation

2

Description

Level of Consciousness

Timepoint

every 2 hours until 24 hours after operation

Method of measurement

observation,clinical examination (GCS)

3

Description

Pruritus

Timepoint

24 hours after operation

Method of measurement

observation,clinical examination

4

Description

Hemodynamic changes

Timepoint

every 2 hours until 24 hours after operation

Method of measurement

clinical examination

5

Description

Respiratory Rate

Timepoint

every 2 hours until 24 hours after operation

Method of measurement

observation,clinical examination

Intervention groups

1

Description

Infusion of morphine as analgesic with PCA pump

Category

Treatment - Drugs

2

Description

Infusion of sufentanil as analgesic with TCI pump

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Kermanshah University of
Medical Sciences

Full name of responsible person

Naser yeganeh - Sharareh Abdolmaleki

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pro-Vice-chancellor for research, Kermanshah
University of Medical Sciences and Health Services

Full name of responsible person

Dr. H.Khazaie

Street address

Pro-Vice-chancellor for research, Kermanshah
University of Medical Sciences and Health Services

City

kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pro-Vice-chancellor for research, Kermanshah University
of Medical Sciences and Health Services

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

Name of organization / entity

Imam Reza Hospital

Full name of responsible person

Sharareh Abdolmaleki

Position

Resident of Anesthesiology

Other areas of specialty/work

Street address

Imam Reza Hospital, Departement of Anesthesia and
intensive care

City

Kermanshah

Postal code

Phone

+98 83 1427 6309

Fax

Email

nyeganeh@kums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Imam reza hospital

Full name of responsible person

Naser Yeganeh

Position

Anesthesiologist/Assisstant Professor

Other areas of specialty/work

Street address

Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Phone

+98 83 1427 6309

Fax

Email

nyeganeh@kums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Imam Reza Hospital

Full name of responsible person

Naser Yeganeh

Position

Anesthesiologist/Assisstant Professor

Other areas of specialty/work

Street address

Departement of Anesthesia and Intensive Care

City

Kermanshah

Postal code

Phone

Fax
Email
nyeganeh@kums.ac.ir
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