

# 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

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## 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

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#### City

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#### Postal code

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**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*