

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Comparison the effect of Gabapentin, Ketamine, Entonox and Dexmedetomidine drugs in controlling pain of burn patients

#### Protocol summary

##### Summary

This study will be done with aim to comparative investigation of Gabapentin, Ketamine, Entonox and Dexmedetomidine drugs effect on controlling pain of burn patients. This study is a double-blind clinical trial. The study population will included all patients referred to burn care of Imam Khomeini hospital in Kermanshah city. Inclusion criteria will included: Burn with grade 2 and 3, burns 20 percent to 50 percent and Exclusion criteria will included: pregnant women, people with any chronic mental illness A total of 100 persons will selected and randomly will assigned into four experiment groups .The first group will receive 1800 mg Gabapentin orally 2 hours before entering the operating room. In the second group ketamine in the form of intravenous in amount of 0.1 to 0.5 mg per kg of body weight will be given one minute before the start of surgery. The third group will receive Dexmedetomidine drug in the form of intravenous infusion and 0.1 to 0.5 mg per kilogram of body weight per minute in ten minutes before the start of surgery and in the fourth group five minutes before the start of surgery, Nitrous Oxide mixed with 70% oxygen through a face mask is prescribed. Each group will receive serum and oxygen through a face mask during surgery. Beginning of the study, half an hour, an hour, two hours, four hours, six hours after surgery vital signs, nausea and vomiting and the pain of four groups patients using the visual analogue scale is measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201605171310N10**

Registration date: **2016-10-13, 1395/07/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-10-13, 1395/07/22

##### Registrant information

###### Name

Alireza Ahmadi

###### Name of organization / entity

Kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3428 2670

###### Email address

info-jivr@kums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### Expected recruitment start date

2016-10-06, 1395/07/15

##### Expected recruitment end date

2017-04-09, 1396/01/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of Gabapentin, Ketamine, Entonox and Dexmedetomidine drugs in controlling pain of burn patients

##### Public title

Comparison the effectiveness of burn drugs on controlling pain of burn patients

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: age between 18 and 60 years; Burn with grade 2 and 3, burns 20 percent to 50 percent; AS A Class 1 and 2 Exclusion criteria: pregnant women; People with any known chronic mental illness; Patients with history of chronic underlying cardiac, lung and kidney disease; patients treated with certain medications such as immunosuppressive medications or chemotherapy or Corticosteroid

### **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: **100**

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

Randomized

### **Randomization description**

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

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Randomly by tossing coin

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

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

Ethics committee of Kermanshah University of Medical Sciences

##### **Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### **City**

Kermanshah

##### **Postal code**

#### **Approval date**

2016-07-13, 1395/04/23

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

kums.rec.1395.258

## **Health conditions studied**

### 1

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

burn

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

T20

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

Burn and corrosion

## **Primary outcomes**

### 1

#### **Description**

The amount of pain

#### **Timepoint**

Beginning of the study, half an hour, an hour, two hours, four hours, six hours after start of surgery

#### **Method of measurement**

Using visual analogue scale (VAS)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The first intervention group will receive 1800 mg Gabapentin orally 2 hours before entering the operating room.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

In the second intervention group ketamine in the form of intravenous in amount of 0.1 to 0.5 mg per kg of body weight will be given one minute before the start of surgery.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

The third intervention group will receive Dexmedetomidine drug in the form of intravenous infusion and 0.1 to 0.5 mg per kilogram of body weight per minute in ten minutes before the start of surgery

#### **Category**

Treatment - Drugs

### 4

#### **Description**

In the fourth intervention group five minutes before the start of surgery, Nitrous Oxide mixed with 70% oxygen through a face mask is prescribed.

#### **Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Emam Khomeini Hospital

**Full name of responsible person**

Simin Chaghazardi

**Street address**

Emam Khomeini Hospital, Naghliyah Street

**City**

Kermanshah

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Sciences

**Full name of responsible person**

Behroz Hamzeh

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Kermanshah University of Medical Sciences

**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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Simin Chaghazardi

**Position**

Resident of Anesthesiology

**Other areas of specialty/work**

**Street address**

Emam Khomeini Hospital, Naghliyah Street

**City**

Kermanshah

**Postal code**

**Phone**

+98 83 3727 9104

**Fax**

**Email**

siminchaghazardi@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Ali Reza Ahmadi

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Emam Khomeini Hospital, Naghliyah Street

**City**

Kermanshah

**Postal code**

**Phone**

+98 83 3727 9104

**Fax**

**Email**

ahmadiar1012@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Simin Chaghazardi

**Position**

Resident of Anesthesiology

**Other areas of specialty/work**

**Street address**

Emam Khomeini Hospital, Naghliyah Street

**City**

Kermanshah

**Postal code**

**Phone**

+98 83 3727 9104

**Fax**

**Email**

siminchaghazardi@gmail.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*