

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

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Phone

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Email address

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Other areas of specialty/work

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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

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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