

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of different doses of ketamine and propofol for sedation and analgesia for changing the dressing in burn patients

Protocol summary

Study aim

Comparison of different doses of ketamine and propofol for sedation and analgesia for changing the dressing in burn patients

Design

Phase III double-blind randomized cross-over trial on 120 patients, randomization with sealed envelopes

Settings and conduct

Patients admitted to the burn ward of Payambar Azam Hospital, Bandar Abbas, not receiving surgical debridement will be included based on the inclusion and exclusion criteria. Patients will receive 1mg midazolam + 0.1-0.2 µ/kg fentanyl as premedication. They will randomly receive A or B method for the first dressing change and the other method for the second time. The outcome assessor and patients will be unaware of the drugs. Patients will undergo monitoring and pulse oximetry. Oxygen saturation, heart and respiratory rate will be assessed at 0 and 10 min after and at the end of the procedure. In case of Ramsay sedation scale (RSS)>3 in each method, 50-100 mg fentanyl will be injected. RSS will be maintained at 3-4.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 15-65 years Second- and third-degree burns Burn area 10-70% Daily dressing change before skin graft in the operation room with ASA class 1-3 Ability to speak and perceive the Persian language
Exclusion criteria: Drug addiction Respiratory and cardiac diseases Renal disorders Hypersensitivity to analgesics, ketamine, and propofol History of psychiatric disorders History of seizure ASA class >3

Intervention groups

Method A: first 1-2 mg/kg intravenous ketamine for induction and then every time the patient's pain was >3 based on his/her facial expression, injection of 1-3 ml propofol 10% Method B: first a mixture of propofol and ketamine each 0.5-1 mg/kg for induction and then every time the patient's pain was >3 based on his/her facial expression, injection of 1-3 ml of the same mixture

Main outcome variables

Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201210049672N2**

Registration date: **2022-03-19, 1400/12/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-19, 1400/12/28**

Update count: **0**

Registration date

2022-03-19, 1400/12/28

Registrant information

Name

Bibimona Razavi

Name of organization / entity

Hormozgan University of Medical Sciences, Faculty of Medicine

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-04-09, 1401/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of different doses of ketamine and propofol for sedation and analgesia for changing the dressing in burn patients

Public title

Comparison of different doses of ketamine and propofol for changing the dressing in burn patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 15-65 years Second- and third-degree burns Burn area of 10-70% Daily dressing change before skin graft in the operating room with American Society of Anesthesiologists (ASA) class 1-3 Ability to speak and perceive the Persian language

Exclusion criteria:

Drug addiction Respiratory and cardiac diseases Renal disorders Hypersensitivity to analgesic drugs, ketamine, and propofol History of psychiatric disorders History of seizure American Society of Anesthesiologists (ASA) class >3

AgeFrom **15 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization with individuals as units of randomization along with allocation concealment: 120 unclear envelopes and 120 cards with the names of the groups (A, B) will be prepared (60 cards for each group). The cards will be put into the envelopes and the envelopes will be sealed and provided to the investigator. Upon entrance of each patient to the study, the envelopes will be shuffled and one will randomly be selected. The patient will be allocated to group A or B based on the card inside the selected envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The solutions will be prepared for injection in advance by an individual not involved in the study and they will only have labels indicating the groups of the study; therefore, the patients, the investigator, the care giver, and the

outcome assessor will be unaware of the injected drugs.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Imam Hossein Blvd., across from Kargaran Sports Complex, Faculty of Medicine

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2021-01-12, 1399/10/23

Ethics committee reference number

IR.HUMS.REC.1399.496

Health conditions studied**1****Description of health condition studied**

Second- and third-degree burns

ICD-10 code

Z48.00

ICD-10 code description

Encounter for change or removal of nonsurgical wound dressing

Primary outcomes**1****Description**

Pain intensity

Timepoint

At the end of the procedure

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Sedation
Timepoint
At the end of the procedure
Method of measurement
Ramsay Sedation Scale

2

Description
Patient satisfaction
Timepoint
At the end of the procedure
Method of measurement
Poor/moderate/good/excellent

3

Description
Surgeon satisfaction
Timepoint
At the end of the procedure
Method of measurement
Poor/moderate/good/excellent

Intervention groups

1

Description
Intervention group: First the patient will receive 1-2 mg intravenous ketamin (MFR:Sterop Co., Belgium) for induction (Each ampule contains 500 mg ketamin/10 ml; therefore, each ml contains 50 mg ketamine, which will be diluted with 4 ml distilled water). During the procedure, whenever the patient's pain score is >3 based on his/her facial expression, 1-3 ml propofol 1% will be injected (each ampule contains 200 mg propofol 1%/20 ml, DoNcKood.phar Co. Korea) in divided intravenous doses (taking 30-100 µ/kg/min as reference based on the interval between injections and the patient's weight).
Category
Treatment - Drugs

2

Description
Intervention group: Ketamine will be diluted with distilled water so that each 1 ml contains 10 mg ketamine (Each ampule contains 500 mg ketamin/10 ml; therefore, each ml contains 50 mg ketamine, which will be diluted with 4 ml distilled water). Then, equal proportions of ketamine and propofol 1% (each ampule contains 200 mg propofol 1%/20 ml) will be mixed in a 10-ml syringe so that each ml of this 0.5% ketofol 0.5% mixture contains 5 mg ketamine and 5 mg propofol. Then, first 0.5-1 mg/kg of the mixture will be injected intravenously for induction. During the procedure, whenever the patient's pain score is >3, 0.1-0.5 mg/kg of the same mixture will be injected.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Payambar Azam Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellery for Research Hormozgan University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
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Imam Hossein Blvd., across from Kargar Sports Complex
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellery for Research Hormozgan University of Medical Sciences
Proportion provided by this source
100
Public or private sector

Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Bibimona Razavi
Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available