Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 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)

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+98 76 3371 0370

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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
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target 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

Bibimona Razavi

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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

Street address

Imam Hossein Blvd., across from Kargaran Sports Complex

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Web page address

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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

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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