Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of analgesic effect of diluted lidocaine spray in reducing pain caused by burning debridement in burning patients admitted to Ali-ebn Abitaleb Hospital in Zahedan between 2022 and 2023

Protocol summary

Study aim

Determining the analgesic effect of diluted lidocaine spray in reducing pain caused by burn debridement in patients hospitalized in the burn department of Ali Ibn Abi Talib Zahedan Hospital.

Design

This study is an interventional type, the study subjects include all patients hospitalized in the burn department of Ali Bin Abi Talib Zahedan Hospital, and they are randomly selected. After entering the study and obtaining consent, demographic and basic information is recorded for all patients This study is a single-blind randomized clinical trial. All patients who meet the entry criteria at the time of the study are considered to enter this study. After obtaining a written consent form and explaining the conditions of the study, the patients are asked to rate their pain level based on the VAS scale. Then they are randomly entered into each of the investigated groups.

Settings and conduct

In the control group, and in the intervention group, lidocaine spray will be prescribed for the patients. Then, each patient is numbered

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Informed and free consent to participate in the study 2. Burn severity above 10% 3. Patients hospitalized in the burn department of Ali Bin Abi Talib Zahedan Hospital Exit criteria: 1. Impaired level of consciousness 2. Hemodynamic disorder 3. Taking drugs or alcohol or pain relievers or painkillers in the last 48 hours. 4. History of taking MAOI, TCA, SSRI, phenothiazines or sleeping pills 5. Suffering from chronic diseases 6. Having asthma 7. Allergy to lidocaine and pethidine 8. Weight more than 100 kg 9. Lack of consent to enter the study 10. Non-cooperation of the patient

Intervention groups

blood pressure • heart beat • Respiration rate • Oxygen saturation of arterial blood • Age and sex Pain based on VAS (0 to 10)

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231126060194N1**
Registration date: **2024-02-14, 1402/11/25**
Registration timing: **retrospective**

Last update: **2024-02-14, 1402/11/25**
Update count: **0**

Registration date

2024-02-14, 1402/11/25

Registrant information

Name

Amirali Divsalar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-05, 1402/09/14

Expected recruitment end date

2024-02-09, 1402/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of analgesic effect of diluted lidocaine spray in reducing pain caused by burning debridement in burning patients admitted to Ali-ebn Abitaleb Hospital in Zahedan between 2022 and 2023

Public title

Evaluation of analgesic effect of diluted lidocaine spray in reducing pain caused by burning debridement in burning patients admitted to Ali-ebn Abitaleb Hospital in Zahedan between 2022 and 2023

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1. Informed and free consent to participate in the study 2. Burn severity above 10% 3. Patients admitted to the burn department of Ali Bin Abi Talib Zahedan Hospital

Exclusion criteria:

1. Impaired level of consciousness (GCS < 15) 2. Hemodynamic disturbance during drug injection (SBP ≤ 90 and PR ≤ 60 and RR ≤ 8 and ≥ 90% (O2) and in patients with blood pressure (SBP ≤ 180) or (SBP ≤ 100)) 3. Use of drugs or alcohol or sedatives or pain relievers in the last 48 hours 4. History of taking MAOI, TCA, SSRI, phenothiazines or sleeping pills 5. Suffering from chronic diseases (congenital or acquired heart diseases, heart failure chronic liver disease, biliary tract diseases, kidney failure and chronic lung disease) according to history and clinical examination 6. Asthma according to history and clinical examination 7. Allergy to lidocaine and pethidine 8. Weight more than 100 kg 9. Lack of consent to enter the study 10. Patient's lack of cooperation

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of patients to two groups is done by permuted block stratified randomization method. In this way, first, eligible referring patients are classified according to age and gender in the order of arrival. Then, based on blocks of 4 (consisting of two groups A and B and two repetitions for each) randomly selected from among all the possible states of permutations, they are assigned to the desired group (2). These blocks were created using statistical software R version 4.0.2

Blinding (investigator's opinion)

Single blinded

Blinding description

In this research, single blinding method is used. So that the patient will not be aware of the intended intervention. Table 1: The practical method of assigning patients to two groups with the permutation block stratified randomization method Age ≤ 30 > 30 gender male female male female Groups BAAB AABB BAAB ABBA BBAA ABAB AABB ABBA ABBA AABB ABAB ABAB BABA BABA BAAB ABBA ABAB ABAB BBAA BAAB ABAB AABB AABB ABBA BBAA AABB BAAB BABA BBAA AABB AABB BAAB BBAA BABA BAAB AABB ABBA ABAB BAAB ABAB

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of zahedan university of medical sciences

Street address

Zahedan University of Medical Sciences Khalij -e- Fars Blvd, Zahedan, Sistan & Balouchestan Province, Islamic Republic of Iran

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9816743463

Approval date

2023-11-12, 1402/08/21

Ethics committee reference number

IR.ZAUMS.REC.1402.327

Health conditions studied

1

Description of health condition studied

Pain after a burn

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes

1

Description

Change in the amount of pain reported by the patient (pain measured by visual observation)

Timepoint

The pain level will be asked and recorded at times 0, 5, 10, 20, 30, and 60 minutes

Method of measurement

VAS criterion

Secondary outcomes

1

Description

Analgesia onset time in patients receiving lidocaine and IV pethidine

Timepoint

Time after starting to receive lidocaine (in minutes)

Method of measurement

Time in minutes

Intervention groups

1

Description

Intervention group: The group that receiving lidocaine medicine

Category

Treatment - Drugs

2

Description

Control group: The group that receiving pethidine drug

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ebn abi taleb hospital of zahedan

Full name of responsible person

masoumeh abbasnejad

Street address

persian gulf Blvd,Ali ebn abitaleb hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Web page address

https://zaums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

1

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

Zahedan University of Medical Sciences

Full name of responsible person

masoumeh abbasnjad

Position

Consultant, Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Latest degree
Subspecialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts after the results are printed

To whom data/document is available
It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used
1- The goal should be clear 2- The possibility of using in future studies

From where data/document is obtainable
Amirali Divsalar amiralidivsalar@gmail.com Zahedan University of Medical Sciences Khalij -e- Fars Blvd, Zahedan, Sistan & Balouchestan Province, Islamic Republic of Iran 98-054-33372013

What processes are involved for a request to access data/document
You can request by sending an email, the documents will be sent within a maximum of one week

Comments