Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of morphine alone with midazolam-morphine combination in reducing pain on Burnt Patients

Protocol summary

Study aim
Comparison of morphine with midazolam-morphine combination in reducing pain in patients with burns
Design
A clinical trial with a control group with a sample size of 100, double blind, randomized
Settings and conduct
This research will be done at Ayatollah Mousavi Hospital in Zanjan. Samples are randomly divided into two groups: one group treated with morphine and placebo and the other group treated with midazolam and morphine. The severity of pain was assessed by the Visual Analogue Scale of pain intensity at the time of arrival, the beginning of dressing and time 0, 20,60,120 minutes, by pain assessor, which was blinded for the type of intervention and drug administered.
Participants/Inclusion and exclusion criteria
Inclusion criteria: GCS 15/15, age between 18 to 65 year old, having physical and mental ability to answer questions, non-inhaler burn, stable hemodynamic status, No addiction Exclusion criteria: pregnancy , allergy to opiums, patients with psychological problems, people with known cardiac, renal and hepatic diseases.
Intervention groups
Group one or intervention: Patients treated with midazolam (manufactured by Elixir Company) at a concentration of half a milligram per milliliter at a dose of 0.08 milliliters per kilogram of body weight intravenously and intravenous morphine sulfate made in Iranian pharmaceutical factories (Darupakhsh) with a concentration of one milligram per milliliter and a dose of 0.1 a milliliter per kilogram of body weight. Group two or control group: Patients treated with distilled water as placebo and intravenous morphine sulfate made by Iranian pharmaceutical factories (Darupakhsh) with a concentration of one milligram per milliliter at a dose of 0.1 milliliter per kilogram of body weight.
Main outcome variables
Pain Relief

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180124038488N2**
Registration date: **2021-06-18, 1400/03/28**
Registration timing: **retrospective**

Last update: **2021-06-18, 1400/03/28**
Update count: **0**
Registration date
2021-06-18, 1400/03/28

Registrant information
Name
Farshad Deilami
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-01-05, 1397/10/15
Expected recruitment end date
2019-10-07, 1398/07/15
Actual recruitment start date
2019-01-05, 1397/10/15
Actual recruitment end date
2020-03-19, 1398/12/29
Trial completion date
2020-03-19, 1398/12/29

Scientific title

Comparison of the effect of morphine alone with midazolam-morphine combination in reducing pain on Burnt Patients

Public title
Comparison of morphine with midazolam-morphine combination in reducing pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Complete awareness and GCS 15/15 Patient between the ages of 18 and 65 years having physical and mental ability to answer questions non-inhaled burn stable hemodinamic status lack of addiction
Exclusion criteria:
pregnancy Allergy to opioids patients with psychological problems people with known cardiac, renal and hepatic diseases.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization will be used to assign individuals to intervention and control groups, because the outcome is evaluated in different time periods and with this method, the number of samples assigned to each of the study groups in different time periods will be equal. To create a random sequence, online randomization will be used, for which the website https://www.sealedenvelope.com is designed to generate a block randomization sequence. Then block size will be 4 and finally 25 blocks will be created and 50 people will be divided into two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients in this study will not know the type of intervention received because both types of drug intervention in the two groups will be performed by injection. Also, assessment of pain intensity (Visual analogue scale) as the main outcome (primary outcome) in both groups It will be done by an observer outside the research team, which is blind to the type of intervention and the allocation of individuals to intervention and control groups. Therefore, it can be said that this study is a double blind study and patients and observer will be unaware of the type of intervention and the allocation of individuals to intervention and control groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Vice Chancellor for Research and Technology,Third Floor, Headquarters of Zanjan University of Medical Sciences, Second Building, Azadi Blvd.
City
Zanjan
Province
Zanjan
Postal code
4513956184
Approval date
2018-12-18, 1397/09/27
Ethics committee reference number
IR.ZUMS.REC.1397.266

Health conditions studied

1

Description of health condition studied
thermal burn
ICD-10 code
T20
ICD-10 code description
Burn and corrosion of head, face, and neck

2

Description of health condition studied
thermal burn
ICD-10 code
T21
ICD-10 code description
Burn and corrosion of trunk

3

Description of health condition studied
thermal burn
ICD-10 code
T22
ICD-10 code description
Burn and corrosion of shoulder and upper limb, except wrist and hand

4

Description of health condition studied
thermal burn
ICD-10 code
T23
ICD-10 code description
Burn and corrosion of wrist and hand

5

Description of health condition studied
thermal burn
ICD-10 code
T24
ICD-10 code description
Burn and corrosion of lower limb, except ankle and foot

6

Description of health condition studied
thermal burn
ICD-10 code
T25
ICD-10 code description
Burn and corrosion of ankle and foot

Primary outcomes

1

Description
Pain relief
Timepoint
At the beginning of the patient's entry into the burn room and at the beginning of the dressing and at times zero, 20, 60 and 120
Method of measurement
Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In group one or intervention, patients were treated with two syringes containing clear liquid prepared in advance by the study supervisor. The number one syringe contains 10 ml of midazolam (made by Elixir Company) with a concentration of half a milligram per milliliter and is injected intravenously at a dose of 0.08 milliliters per kilogram of body weight for one minute. In the second syringe, 10 ml of intravenous morphine sulfate solution made by Iranian pharmaceutical factories (Darupakhsh) with a concentration of one mg per ml, which is injected at a dose of 0.1 milliliter per kilogram of body weight. Intravenous midazolam is injected only once.
Category
Treatment - Drugs

2

Description
Control group: In group two or control group, patients were treated with two syringes containing 10 ml of clear liquid that had been prepared by the study supervisor. In syringe number one, there was ten milliliters of distilled water as a placebo, which is injected intravenously at a dose of 0.08 milliliters per kilogram of body weight, and in syringe number two, ten milliliters of intravenous morphine sulfate solution made by Iranian pharmaceutical factories (Darupakhsh) with a concentration of one milligram per milliliter, which is injected at a dose of 0.1 milliliter per kilogram of body weight
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Mousavi Hospital
Full name of responsible person
Mohsen Salehi
Street address
In front of the University of Basic Sciences, Gavazang Road
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

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

No

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Dr Mohsen Salehi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Mohsen Salehi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Farshad Deilami

Position

Emergency medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

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farshaddaylami@gmail.com

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

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

May 2020

To whom data/document is available

Only for researchers working in medical universities

Under which criteria data/document could be used

No specific conditions

From where data/document is obtainable

Dr Mohsen Salehi, Assistant Professor of Emergency Medicine Department, Zanjan University of Medical Sciences, m.salehi@zums.ac.ir

What processes are involved for a request to access data/document

Sending an e-mail containing a formal application, along with providing job approvals

Comments