

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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 opioms, 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

Country

Iran (Islamic Republic of)

Phone

+98 24 3347 0753

Email address

farshaddaylami@gmail.com

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 hemodynamic 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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Zanjan

Province

Zanjan

Postal code

4513956184

Phone

+98 24 3377 0801

Email

m.salehi@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

Street address

Zanjan University of Medical Sciences, Azadi Boulevard

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Shoghli@zums.ac.ir

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

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 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, Zanzan 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