

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

A clinical trial comparison between antianalgesic effect and side effects of Fentanyl , Morphine and Pethidine for burn injury at first hour admission in hospital

Protocol summary

Study aim

Investigating the analgesic effect of three different drugs to control the pain of burn patients, and ultimately using the most effective drug with the least side effects.

Design

78 burn patients randomly will be divided into three groups of 26 people on the first day of visiting emergency room; Systematic randomization method is created using the randomization command in the Excel program (Random Between).The randomization is such that the first person is placed in group A, the second person is in group B, and the third one is in group C, and in the same way, the next patient is in group A and... After the injection of the medicine, the intensity of the pain will be recorded in 15, 30, 45 and 60 minutes. The reduction of the patient's pain by more than 3 points means the beginning of response to the treatment.

Settings and conduct

A clinical trial & double-blind study, so that the patient and the nurse don't know the type of medicine received. The study is carried out in the emergency department of Taleghani Hospital in Ahvaz on burn patients.

Participants/Inclusion and exclusion criteria

Patients from the age group of 18-55 years with 2nd and 3rd degree burns, burn extent of 30-60% and pain intensity of at least 6 out of 10 based on the NRS criteria are included in the study. Patients who have a history of allergy to any of the above drugs, addicts, pregnant women and people with a low level of consciousness are excluded.

Intervention groups

We give 0.1mg/kg of morphine to group A , 1.5mcg/kg fentanyl to group B and 0.75mg/kg pethidine to the next one.

Main outcome variables

At the end of the study, the obtained pain numbers are evaluated and compared based on the NRS criteria;

Another variable that is important to us is the possible side effects of the drug within an hour after the injection, which we must monitor the patient carefully.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230704058673N2**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

mojtaba sasani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3392 4155

Email address

sasani-m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparison between antianalgesic effect and side effects of Fentanyl , Morphine and Pethidine for burn injury at first hour admission in hospital

Public title

Antianalgesic effect and side effects of Fentanyl , Morphine and Pethidine for burn injury

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

patients from 18-55 years old with 2-3th grade of burning with extent of burn 30-60% pain degree 6-10 according to NRS

Exclusion criteria:

pregnant women allergy to mentioned opioids addicts GCS<15

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Systematic randomization method is used for random allocation. The randomization is such that the first person is placed in group A, the second person in group B and the third person in group C, and in the same way the next references are in group A and...

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be done under circumstances which the patient and the nurse don't have information about the group of antianalgesic and they just know the A , B ,C group.

Placebo

Not used

Assignment

Parallel

Other design features

We record the pain degree after 15-30-45 & 60 minutes.

Secondary Ids

empty

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

Ethics committee of Jondishapur University of Medical Sciences

Street address

Farvardin Avn , Ahvaz Jondishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2022-11-30, 1401/09/09

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.136

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

burning

ICD-10 code

T20-T25

ICD-10 code description

Burns and corrosions of external body surface, specified by site

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

Pain intensity in burn patients

Timepoint

Measurement of pain intensity at the beginning of the study (before the intervention) and 15, 30, 45 and 60 minutes after the intervention

Method of measurement

NRS criteria

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1:one dose of 0.1 mg/kg of morphine is injected intravenously to the first group.

Category

Treatment - Drugs

2

Description

Intervention group 2: One dose of 1.5 mcg/kg of fentanyl is injected intravenously to the second group.

Category

Treatment - Drugs

3

Description

Intervention group 3: One dose of 0.75 mg/kg of pethidine is injected intravenously to the third group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Mojtaba Sasani

Street address

Hejrat sq,Padadshahr2 Ave, Taleghani Hospital

City

Ahvaz

Province

Khouzestan

Postal code

4561355

Phone

+98 61 3554 7996

Email

sasani-m@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi moghaddam

Street address

Golestan Ave,Jondishapur university

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3336 2414

Fax

+98 61 3336 1544

Email

itc@ajums.ac.ir

Web page address

<https://vchresearch.ajums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mojtaba Sasani

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Golestan Ave,Jondishapur University

City

Ahvaz

Province

Fars

Postal code

6135715794

Phone

+98 61 3571 5794

Email

Drsasani72363@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mojtaba Sasani

Position

professor assistant

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Golestan Ave,Jondishapaur University

City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 915 512 0247
Email
Drsasani72363@gmail.com

Khouzestan
Postal code
6135715794
Phone
+98 61 3392 4155
Fax
Email
sasani-m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mojtaba Sasani
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Goletan . farvardin bolvar . goletan hospital .
emergency department
City
Ahvaz
Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available