

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of the effect of intravenous fentanyl plus midazolam on wound repair score of second degree burn wounds of trunk: a Randomized clinical trial

Protocol summary

Summary

Morphine and μ agonists have reduced inflammatory mediators and accelerated epithelialization and wound closure in animal and human wound model studies. This randomized clinical trial evaluates wound healing with sedating patients by usage of fentanyl plus midazolam, compared to routine morphine in Shahid Sadoughi burn hospital in Yazd, Iran. Patients aged 15-55 years old with second degree burn who need daily dressing change are enrolled in the study in their second day of admission till at least 65 patients get enrolled in each group. Patients with comorbidities, immune deficiency or opiates addiction history are excluded. Patients are allocated to intervention or placebo group randomly. All patients receive 5 mg morphine sulfate 15 minutes before changing wound dressing. Three minutes before dressing change, intervention group receive 5 μ g Fentanyl plus 2 mg Midazolam and control group receive 5 cc sterilized water. The biggest wound of patient which is larger than 5 percent will be evaluated daily in first week and then every 2 weeks till 3 months according to Vancouver score, clinical healing time and wound infection. Pain score will be evaluated using Visual Analog Scale, 5 minutes before and after dressing change in both groups. Patients, nurses who change the dressing and data collector and analyzers are blind to allocation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051811921N1**
Registration date: **2016-06-17, 1395/03/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-17, 1395/03/28

Registrant information

Name

Sima Valizadeh

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3823 3040

Email address

valizade@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of intravenous fentanyl plus midazolam on wound repair score of second degree burn wounds of trunk: a Randomized clinical trial

Public title

The effect of fentanyl plus midazolam injection during

wound dressing change on the healing of burn wounds

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Patients aged 16-55 years with second degree thermal burn; require daily dressing change; being in second day of admission; having at least one wound larger than 5 % of body surface area; signing informed consent. Exclusion Criteria: affected by chronic disease (Diabetes mellitus, cardiovascular disease, Hepatic disease, Renal disease); Immune deficiency(corticosteroid, chemotherapy); history of anaphylaxis to sedation drugs, Opiates, benzodiazepines; difficult airway according to mallampati score; history of opiates addiction

Age
From **16 years** old to **55 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Every Patient is allocated to group one or two by using a sealed pocket. The code of 1 or 2 will be written on patient's questionnaire. Drugs 1 and 2 is prepared in completely the same syringes by another colleague. The patient receives drug 1 or 2 according to his/her group. None of the colleagues (the nurse who change the dressing, the one who follow up and collect data, the one who analyze the data) nor the patients are informed about coding. That one who prepares the syringes does not take part in changing the wound dressing, collection or analyzing the data.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

Central building of Yazd Shahid Sadoughi University

of Medical Sciences, Bahonar Square

City

Yazd

Postal code

Approval date

2015-03-14, 1393/12/23

Ethics committee reference number

17/1/3315/پ

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

(T20-T25)

ICD-10 code description

Burns and corrosions of external body surface

Primary outcomes

1

Description

wound repair score

Timepoint

every 2 weeks from week zero till 12th week

Method of measurement

Vancouver score

2

Description

Time to healing

Timepoint

every 2 weeks from week 1 till 12th week

Method of measurement

According to clinical judgment of plastic surgeon regarding discharge, pain or redness of the burned area. When plastic surgeon confirms clinical healing, that time is documented as the healing time

Secondary outcomes

1

Description

pain score

Timepoint

5 minutes before and after changing dressing every 2 weeks from week zero till 12th week

Method of measurement

Visual Analogue Scale

2

Description

wound infection

Timepoint

daily in first week then on 14th day

Method of measurement

According to clinical judgment of plastic surgeon regarding discharge and erythema of wound

Intervention groups

1

Description

Intervention group: 3 minutes before daily changing the wound dressing, 50 microgram Fentanyl (Dorsa Darou) plus 2 miligram Midazolam (Dorsa Darou) will be infused intravenously .All patients receive 5 mg morphine sulfate intravenously, 10-15 minutes before changing of wound dressing. Intervention will be performed daily for 7 days. Cardiac monitoring and pulse oximetry will be done for all patients. Resuscitation unit will be prepared for each patient. The follow up will be as the same for both groups.

Category

Treatment - Drugs

2

Description

Placebo group: 5 cc strilled water in the same 5 cc syringe will be infused intravenously. All patients receive 5 mg morphine sulfate intravenously 10-15 minutes before changing dressing . All patients are cardiac monitored and also by pulse oximeter. resuscitation unit will be prepared for every patient. Intervention by placebo will be done daily for 7 days. The follow up will be the same for both groups.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi burn hospital

Full name of responsible person

Edalatkhah MD

Street address

Moallem Alley, Shahid Paknejad Street, Yazd, Iran

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Amir Hooshang Mehrparvar

Street address

Central building of Yazd Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Yazd Shahid Sadoughi University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Sima Valizadeh

Position

Researcher

Other areas of specialty/work

Street address

Central building of Yazd Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City

Yazd

Postal code

Phone

+98 35338233040

Fax

Email

valizade@ssu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Abbas Edalatkhah MD

Position

Emergency medicine Sprcialist

Other areas of specialty/work

Street address

Central building of Yazd Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City

Yazd
Postal code
Phone
+98 35 3823 3040
Fax
Email
abbas_edalatkah@yahoo.com
Web page address

Postal code
Phone
+98 35 3823 3040
Fax
Email
valizade@ssu.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Yazd Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Sima Valizadeh, MD
Position
Researcher, Medical Doctor
Other areas of specialty/work
Street address
Central building of Yazd Shahid Sadoughi University
of Medical Sciences, Bamonar Square, Yazd, Iran
City
Yazd

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty