Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Effect of inhaled Entonox on relief pain, anxiety and hemodynamic factors in burned patients during dressing changes in burning ward of Imam Reza (AS) in Birjand in 1394

Protocol summary

Summary

The aim of this study is to evaluate the effect of inhaled Entonox on relief pain, anxiety and hemodynamic factors burn patients during dressing changes in burn ward of Imam Reza (AS) is in Birjand in 1394. The inclusion criteria for patients with burn percentage between 15% to 60% and not addicted to drugs and exclusion criteria are dangerous reactions in the intervening time will be considered. The study population will be burn unit patients in Birjand Imam Reza Hospital . In this study, 80 patients (according to formula) that they have15 to 60 percent burning and burn two degree will be used. they should passed 24 to 48 hours after their burn. The design of the study, which randomized, double-blind, placebo control is performed. Patients were randomly divided into two groups and the written agreement with the consent of the samples will be taken. And to a questionnaire study of pain, anxiety and hemodynamic factors for the patients and the degree of extraction of these factors and after the intervention group and the control group by inhaling Entonox put under oxygen inhalation and put in the questionnaire again by patients and factors to examine and record the data will be analyzed and analyzed. 8 months time will be considered intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040521390N2**
Registration date: **2015-12-15, 1394/09/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-15, 1394/09/24

Registrant information

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-03-21, 1395/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of inhaled Entonox on relief pain, anxiety and hemodynamic factors in burned patients during dressing changes in burning ward of Imam Reza (AS) in Birjand in 1394

Public title

Entonox inhalation effect on pain relief

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 20 and 60 years; there is

no underlying medical or psychiatric conditions other than burn, burn percentage between 15% to 60%, though second-degree burn, not addicted to drugs or opium; Exclusion criteria: presence of hazardous reactions during intervention.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Birjand University of Medical Science

Street address
Birjand University of Medical Science, Ghafari Street, Birjand

City
Birjand

Postal code

Approval date
2015-05-25, 1394/03/04

Ethics committee reference number
IR.BUMS.1394.37

Health conditions studied

1

Description of health condition studied
Burn, Vital Sign,Anxiety, Pain

ICD-10 code
T21, T22,

ICD-10 code description
Burn and corrosion of trunk, Burn and corrosion of shoulder and upper limb, except wrist and hand, Burn and corrosion of wrist and hand, Burn and corrosion of hip and lower limb, except ankle and foot, Burn and corrosion of ankle and foot, Tachycardia, un

Primary outcomes

1

Description
Pain

Timepoint
30 Minutes befor, At the time of intervention and 30 Minutes after intervention

Method of measurement
VAS Scale

2

Description
Anxiety

Timepoint
30 Minutes befor, At the time of intervention and 30 Minutes after intervention

Method of measurement
BSPAS Scale

3

Description
Hemodynamic Factors

Timepoint
30 Minutes befor, At the time of intervention and 30 Minutes after intervention

Method of measurement
Mmhg for blood preseure, Rate in minute for plus, Percent of blood oxygen saturation

Secondary outcomes

empty

Intervention groups

1

Description
Group Intervention: The intervention group Entonox we have a mixture of 60% nitrogen and 40% oxygen is used. For two minutes before dressing for inhaled through a mask at the time of dressing change will be simple. This process will continue during dressing changes. And pain, anxiety and changes in hemodynamic parameters in three stages once again exactly 30 minutes before the intervention and once in the intervening time will be 30 minutes after the intervention.

Category
Treatment - Drugs

2

Description
Control group: The control group of oxygen will be used as a placebo. For two minutes before dressing will be used at the time of dressing changes and pain, anxiety

and changes in hemodynamic parameters will be recorded. And the results are compared.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Burn Ward, Imam Reza Hospital, Birjand

Full name of responsible person

Hassan Eslami Aliabadi

Street address

Burn Ward, Imam Reza Hospital, Ayatolahe Taleghani Street, Birjand, South Khourasan, Iran

City

Ferdows

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Committee, Birjand University of Medical Sciences

Full name of responsible person

DR. Asghar Zarban

Street address

Research Committee, Birjand University of Medical Sciences, South Khorasan, Iran

City

Birjand

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Committee, Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Hassan Eslami Aliabadi

Position

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Other areas of specialty/work

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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