Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of comparison the Effectiveness between Entonox and Midazolam-Fentanyl in Sedation for Cardioversion in patients with Tachydysrythmia

Protocol summary

Summary

In this study we compared Entonox effectiveness of sedation for Cardioversion with standard intravenous sedation, midazolam & fentanyl. Inclusion criteria was: age over 18 years, symptomatic Tachydysrythmia. Exclusion criteria was: any situation that cause air entrapment in body. Forty four patients with symptomatic Tachydysrythmia divided in two groups randomly. Midazolam plus Fentanyl administered intravenously in first group and Entonox administered with demand valve mask in second group. Time of sedation, time of end of sedation, complications was recorded. Level of sedation noted according to Richmond sedation and analgesia score and at the end of sedation, pain score recorded in each group with visual analogue scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202269147N1**
Registration date: **2014-05-13, 1393/02/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-13, 1393/02/23

Registrant information

Name

Sina Saghari

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison the Effectiveness between Entonox and Midazolam-Fentanyl in Sedation for Cardioversion in patients with Tachydysrythmia

Public title

Sedation for Cardioversion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; symptomatic Tachydysrythmia Exclusion criteria: Drug sensitivity; pneumothorax; small bowel obstruction; chronic obstructive pulmonary disease; head trauma with decreased level of consciousness; Maxiofacial Injury; air emboli; inner ear infection

Age

From **18 years** old

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahvaz University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Jundishapur University of Medical sciences, University City, Ahvaz, Khuzestan, Iran
City
Ahvaz
Postal code
Approval date
2012-06-21, 1391/04/01
Ethics committee reference number
ETH-534

Health conditions studied

1

Description of health condition studied
Sedation for Cardioversion
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
After Sedation
Method of measurement
Visual Analogue Scale

2

Description
Sedation Level
Timepoint
During Sedation
Method of measurement
Richmond analgesia and sedation Scale

Secondary outcomes

1

Description
Respiratory arrest
Timepoint
During sedation
Method of measurement
Patient Respiration observe

2

Description
More Doses
Timepoint
During sedation
Method of measurement
More than primery standard dose

3

Description
Time of Sedation
Timepoint
From onset of sedation untill return to primery level of consiousness
Method of measurement
Minutes

Intervention groups

1

Description
Control group sedated with Midazolam (0.15 milligrams per kilograms) plus Fentanyl (1.5 micrograms per kilograms)
Category
Treatment - Drugs

2

Description
Intervention group sedated with Entonox by demand valve mask.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini Hospital
Full name of responsible person
Sina Saghari
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Shahid Ahvazian avenue, 24 metri street, Ahvaz, Khuzestan, Iran
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Miss. Jaderi
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Vice Chancellor for Research and Technology, Jundishapur University of Medical Sciencs, University city, Ahvaz, Khuzestan, Iran
City
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Grant name
Grant code / Reference number
U91080
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
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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