

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

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

#### 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 Tachydysrhythmia. Exclusion criteria was: any situation that cause air entrapment in body. Forty four patients with symptomatic Tachydysrhythmia 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

+98 61 1375 7129

##### Email address

saghari.s@ajums.ac.ir

##### 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 Tachydysrhythmia

##### Public title

Sedation for Cardioversion

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; symptomatic Tachydysrhythmia 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

**Street address**

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

**Street address**

Vice Chancellor for Research and Technology,  
Jundishapur University of Medical Sciences, University  
city, Ahvaz, Khuzestan, Iran

**City**

Ahvaz

**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**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Sina Saghari

**Position**

Resident

**Other areas of specialty/work**

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**Position**

Associate professor

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**Web page address**

**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*