# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Comparison of Remifentanil with Fentanyl/Midazolam for Moderate Sedation for Closed Reduction of Anterior Shoulder Dislocation in Adults in the ED: a Randomized Controlled Trial

## Protocol summary

**Summary**

Objective: The aim of this study is to compare the efficacy of a pure analgesia- based sedation regimen with Remifentanil with a conventional regimen consisting of Fentanyl / Midazolam for moderate sedation for reduction of anterior shoulder dislocation in adults in ED. Setting: This study is conducted in the ED of a university-affiliated tertiary care medical center over a 9-month period between February 2, 2013 and October 23, 2013. Design:A prospective, randomized clinical trial. Participants:42 intent-to-treat American Society of Anesthesiologists (ASA) class I–II adult patients undergoing moderate sedation for closed shoulder reduction will be randomly allocated into two groups. Intervention: Group 1 will receive R (1 µg/kg and repeated additional doses of 1 µg/kg/min), while those in group 2 will receive F (1.5 µg/kg) plus M (0.1 mg/kg). Main outcome measures: Primary end-points are pain score, procedure time and patient satisfaction, and incidence of respiratory adverse events. Secondary end points included non respiratory adverse events.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2013011312115N1**
Registration date: **2014-05-11, 1393/02/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2014-05-11, 1393/02/21

**Registrant information**

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Hamid Zamani Moghadam
**Name of organization / entity**
Mashhad University of Medical Sciences
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**Recruitment status**

**Recruitment complete**

**Funding source**

Mashhad University of Medical Sciences

**Expected recruitment start date**

2013-02-02, 1391/11/14

**Expected recruitment end date**

2013-10-23, 1392/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Remifentanil with Fentanyl/Midazolam for Moderate Sedation for Closed Reduction of Anterior Shoulder Dislocation in Adults in the ED: a Randomized Controlled Trial

**Public title**

Remifentanil for Moderate Sedation for Shoulder Reduction in the ED

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

INCLUSION CRITERIA: Those aged 18–64 years with anterior shoulder dislocation, requiring closed reduction

with physical condition I (healthy and normal patients without previous medical history) and II (patients with mild systemic disease with no functional limitation) according to the classification system of American Society of Anesthesiologists (ASA) will be selected. EXCLUSION CRITERIA: The exclusion criteria included age <18 years and >64 years; History of allergy to benzodiazepines and narcotics; Prolonged use of opioids; Alcohol usage; Sleep obstructive apnea syndrome; Maxillofacial malformations with high probability of failure in maintaining the airway; Pregnant patients; Anterior dislocation requiring referral to orthopedic operating room; Patients with severe trauma; Patients in septic shock; Patients with advanced Heart disease; Kidney failure; Pneumonia; Uncontrolled seizures; Patients not willing to participate in the study.

**Age**
From **18 years** old to **64 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **42**

**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**
Mashhad University of Medical Sciences Ethics Committee

**Street address**
Vice chancellor for research Mashhad Univercity of Medical Sciences, Ghoreishi building, Daneshgah avenue, Mashhad, Iran.

**City**
Mashhad

**Postal code**
91735-951

**Approval date**
2012-11-04, 1391/08/14

**Ethics committee reference number**
91/570419

## Health conditions studied

### 1

**Description of health condition studied**
Anterior Shoulder Dislocation

**ICD-10 code**
s43.0

**ICD-10 code description**
Glenohumeral Joint

## Primary outcomes

### 1

**Description**
Pain Perception

**Timepoint**
During Intervention

**Method of measurement**
Visual Analog Scale 100mm

### 2

**Description**
Respiratory Adverse Events

**Timepoint**
During Intervention

**Method of measurement**
The need for supplemental oxygen, Ventilation with a bag-mask, Maneuver practices for maintaining the airway open, Insertion of airway, Respiratory stimulation, Respiratory depression with SpO2 <92% in any time of intravenous administration of the drug until hospital discharge

### 3

**Description**
Procedure Time

**Timepoint**
During Intervention

**Method of measurement**
From the begining of sedatiion till end of reduction

### 4

**Description**
Patient Consent

**Timepoint**
After Intervention

**Method of measurement**
Likert Scale

## Secondary outcomes

### 1

**Description**
Non Respiratory Adverse Events

**Timepoint**
During Intervention

**Method of measurement**
Dysphoria, Vomiting, Headache, Myoclonus, Nausea, Stiffness, Rash, Cough, Bronchospasm, Laryngospasm, Stridor, Apnea, Seizures, Rash, Restlessness, Aspiration

## Intervention groups

### 1

**Description**
Patients in control group will recieve single dose fentanyl 1.5 microg/kg slowly via intravenous infusion over 30 seconds from the form of injection solution 0.05 mg/ml plus single dose midazolam 0.1 mg/kg slowly via intravenous infusion over 2 minutes from the form of injection solution 1 mg/ml.
**Category**
Treatment - Drugs

### 2

**Description**
In the intervention group the patients will receive remifentanil 1 microg/kg slowly via intravenous injection over 30 seconds and repeated doses every 1 minute titrated to effect from the form of injection,powder for reconstitution: 1mg, diluted to a final concentration of 50 microg/ml.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Emam Reza Hospital
**Full name of responsible person**
Dr.Zamani Moghadam.H emergency medicine specialist
**Street address**
Emam Reza Hospital, Emam Reza square,Avicina avenue, Mashhad, Iran.
**City**
Mashhad

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Mashhad University of Medical Sciences
**Full name of responsible person**
Dr Mohsen Tafaghodi
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Vice chancellor for research, Mashhad Uvivercity of Medical Sciences, Ghoreishi building, Daneshgah avenue, Mashhad.
**City**
Mashhad
**Grant name**
اعتبارپژوهشی
**Grant code / Reference number**
010361
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Mashhad 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 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*