

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 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

Name

Hamid Zamani Moghadam

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 58 1221 1537

Email address

zamanimh@mums.ac.ir

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 University 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 beginning of sedation 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 receive 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 remifentanyl 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

Street address

Vice chancellor for research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah avenue, Mashhad.

City

Mashhad

Grant name

اعتبار پژوهشی

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

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

Zamani Moghadam Hamid

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

Street address

Emam Reza Hospital, Emam Reza square, Avicina avenue, Mashhad.

City

Mashhad

Postal code

Phone

+98 51 1852 5312

Fax

Email

zamanimh@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Azadeh Tafakori

Position

Resident of Emergency Medicine

Other areas of specialty/work

Street address

Emam Reza Hospital, Emam Reza square, Avicina avenue, Mashhad.

City

Mashhad

Postal code

Phone

+98 51 1852 5312

Fax

Email

dr.azadeh.tafakori@hotmail.com

Web page address

Phone

+98 51 1852 5312

Fax

Email

zamanimh@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zamani Moghadam Hamid

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

Street address

Emam Reza Hospital, Emam Reza square, Avicenna
avenue, Mashhad .

City

Mashhad

Postal code

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