

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of Remifentanil with Combined Propofol and Fentanyl Medications for Sedative and Analgesic Effects on Patients with Anterior Shoulder Dislocation Treated by Closed Reduction, A Double-Blind Randomized Clinical Trial

Protocol summary

Study aim

A comparative study on the sedative and analgesic effects of remifentanil and combined propofol and fentanyl in patients with shoulder dislocation

Design

This study is performed on 60 patients referring to the emergency department of Rasht Poursina hospital, with acute anterior shoulder dislocation requiring closed reduction. The patients are placed in two groups by random block method. Random sequences are generated with a 1:1 ratio using the random generator program. Generated sequences or labels A and B are put in sealed envelopes at the emergency nursing station. This study is done in phase three.

Settings and conduct

This study is performed on the patients of emergency department of Poursina Hospital in Rasht, with shoulder dislocation. After receiving the desired sedative drug (remifentanil or combined fentanyl and propofol), the patients will be examined in terms of success in reducing shoulder joint dislocation, complications (agitation, nausea, vomiting, apnea), pain (score 1 to 10 based on VAS criteria), trouble-free shoulder reduction, the length of stay in the emergency ward for recovery, the duration of the analgesic and sedative effects, and the need for re-injection. The present study is double-blind. An emergency medical specialist working in the hospital gives drugs according to the generated sequences in the same covered encoded syringes to the related residents without having any information on them, and if re-injection is necessary, s(he) will give them the medicine. Also, the patient and the person evaluating the outcome are not aware of the type of injectable drugs.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: The patients referring to the emergency ward of Rasht Poursina hospital, with acute

anterior shoulder dislocation requiring closed reduction.

Exclusion Criteria: The patients who have been diagnosed with fracture-dislocation of the shoulder joint, except those suffering from Hill-Sachs lesions The patients with decreased Glasgow coma scale (GCS) The patients with immature skeletal system (open epiphysis) or the patients who have undergone surgery beforehand and have had a fracture in the same shoulder The patients who are allergic to soy and eggs The patients with reduced blood pressure The patients with heart failure The patients over the age of 60 and under the age of 15 years

Intervention groups

Intervention group: Remifentanil group. A group of patients referring to the emergency ward of Poursina hospital in Rasht, with an acute anterior shoulder dislocation needing closed reduction, taking remifentanil drug for relieving pain. Control group: Combined propofol and fentanyl. A group of patients referring to the Emergency Department of Poursina hospital in Rasht, with acute anterior shoulder dislocation requiring closed reduction, taking combination of propofol and fentanyl for relieving pain.

Main outcome variables

Side effects; starting time for the reduction after the medication injection; severity of pain; trouble-freeness in joint reduction; stay length in the emergency ward; the need for re-injection of the medication; the duration of analgesic effect after injection

General information

Reason for update

Acronym

PSA, VAS, ED

IRCT registration information

IRCT registration number: **IRCT20110818007369N6**

Registration date: **2018-02-21, 1396/12/02**

Registration timing: retrospective	age of 60 and under the age of 15 years
Last update: 2018-02-21, 1396/12/02	Age
Update count: 0	From 15 years old to 60 years old
Registration date	Gender
2018-02-21, 1396/12/02	Both
Registrant information	Phase
Name	3
Firouz Behboudi	Groups that have been masked
Name of organization / entity	• Participant • Investigator • Outcome assessor
Gilan University of Medical Sciences	
Country	Sample size
Iran (Islamic Republic of)	Target sample size: 60
Phone	Randomization (investigator's opinion)
+98 13 3336 8773	Randomized
Email address	Randomization description
info@gtrc.ir	According to the sample size calculated in this study, which equals to 30 patients in each group, they are randomly placed in two groups by random block method. Random sequences are generated with a 1:1 ratio using the random generator program. Generated sequences or labels A and B are put in sealed envelopes at the Emergency Nursing Station.
Recruitment status	Blinding (investigator's opinion)
Recruitment complete	Double blinded
Funding source	Blinding description
	The present study is double-blind. An emergency medical specialist working in the hospital gives drugs according to the generated sequences in the same covered encoded syringes to the related residents without having any information on them, and if re-injection is necessary, s(he) will give them the medicine. Also, the patient and the person evaluating the outcome are not aware of the type of injectable drugs.
Expected recruitment start date	Placebo
2017-10-23, 1396/08/01	Not used
Expected recruitment end date	Assignment
2017-12-21, 1396/09/30	Parallel
Actual recruitment start date	Other design features
empty	-
Actual recruitment end date	Secondary Ids
empty	empty
Trial completion date	Ethics committees
empty	1
Scientific title	Ethics committee
Comparison of Remifentanyl with Combined Propofol and Fentanyl Medications for Sedative and Analgesic Effects on Patients with Anterior Shoulder Dislocation Treated by Closed Reduction, A Double-Blind Randomized Clinical Trial	Name of ethics committee
	Ethics Committee of Guilan University of Medical Sciences
Public title	Street address
Comparison of Remifentanyl with Combined Propofol and Fentanyl Medications for Sedative and Analgesic Effects in the Treatment of Shoulder Dislocation	Deputy of Research and Technology, opposite to 17 Shahrivar Hospital, Shahid Siadati St., Namjoo Ave.
Purpose	City
Treatment	Rasht
Inclusion/Exclusion criteria	Province
Inclusion criteria:	Guilan
The patients referring to the emergency department of Poursina hospital with acute anterior shoulder dislocation requiring closed reduction	
Exclusion criteria:	
The patients who have been diagnosed with fracture-dislocation of the shoulder joint, except those suffering from Hill-Sachs lesions The patients with decreased GCS and unstable hemodynamic status The patients with immature skeletal system (open epiphysis) or the patients who have undergone surgery previously and have had a fracture in the same shoulder The patients who are allergic to soy and eggs The patients with reduced blood pressure (Systolic Blood Pressure<90 mm Hg) The patients with heart failure The patients over the	

Postal code
4144666949

Approval date
2017-10-21, 1396/07/29

Ethics committee reference number
IR.GUMS.REC.1396.271

Health conditions studied

1

Description of health condition studied

anterior shoulder dislocation

ICD-10 code

S43.0

ICD-10 code description

Unspecified subluxation and dislocation of shoulder joint

Primary outcomes

1

Description

Amount of side effects following drug injection such as agitation, nausea, vomiting, and apnea

Timepoint

1, 5, 10 and 20 minutes after shoulder reduction

Method of measurement

Based on the resident report

2

Description

Starting time of reduction after the drug injection

Timepoint

1, 5, 10 and 20 minutes after shoulder reduction

Method of measurement

Since drug injection until patient sedation in seconds

3

Description

Severity of pain

Timepoint

1, 5, 10 and 20 minutes after shoulder reduction

Method of measurement

The severity of pain before, during, and after joint reduction is measured according to the visual analogue scale based on the patient's statement.

4

Description

Amount of trouble-freeness in the shoulder joint reduction

Timepoint

1, 5, 10 and 20 minutes after shoulder reduction

Method of measurement

Based on the resident report

5

Description

Stay length in the emergency ward

Timepoint

1, 5, 10 and 20 minutes after shoulder reduction

Method of measurement

Since the beginning of injection until the end of the recovery (full consciousness) in the patient in minutes

6

Description

The need for re-injection of the drug

Timepoint

1, 5, 10 and 20 minutes after shoulder reduction

Method of measurement

The inadequacy of the sedative and analgesic effects leading to re-inject repeated dose of the drug

7

Description

Duration analgesic effect after the drug injection

Timepoint

1, 5, 10 and 20 minutes after shoulder reduction

Method of measurement

Duration of the sedative and analgesic effects after the injection in minutes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Remifentanyl (1 µg/kg) will be injected intravenously. Remifentanyl (0.5 µg/kg) can be repeated three times at the most, and if needed, the drug will be injected after measuring visual analogue scale.

Category

Treatment - Drugs

2

Description

Control group: A combination of propofol (1 mg/kg) and fentanyl (1 µg/kg) will be injected intravenously. For reinjection, the dose of propofol is 0.5 mg/kg, and if needed, the drugs will be injected after measuring visual analogue scale.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

Marjan Aghajani Nargesi

Street address

Poursina Hospital, Poursina Crossroads, Namjoo Ave.

City

Rasht

Province

Guilan

Postal code

4193713194

Phone

+98 13 3336 8773

Fax

+98 13 3333 9842

Email

info@gtrc.ir

Web page address

<http://www.gums.ac.ir/poursina>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr. Shadman Nemati

Street address

Opposite 17 Shahrivar Hospital, Shahid Siadati St.,
Namjoo Ave.

City

Rasht

Province

Guilan

Postal code

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Phone

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Fax

+98 13 3332 4168

Email

research@gums.ac.ir

Web page address

<http://www.gums.ac.ir/research>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Marjan Aghajani Nargesi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Unit 2, 1st Floor, No. 11, St. 186, Guilan Blvd., Golsar

City

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Province

Guilan

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4166813315

Phone

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Email

info@gtrc.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Vahid Monsef Kasmaei

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Poursina Hospital, Poursina Crossroads, Namjoo Ave.

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Email

vmonsef@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Marjan Aghajani Nargesi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Unit 2, 1st Floor, No. 11, St. 186, Guilan Blvd., Golsar

City

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Province

Guilan

Postal code

4166813315

Phone

+98 13 3377 4858

Email

info@gtrc.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available