

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### Comparison of Ketamin/Propofol (Ketofol) and Etomidate /Fentanyl (Etofen) combinations for procedural sedation and analgesia of anterior shoulder dislocation reduction in Emergency Department: A Randomized Clinical Trial

#### Protocol summary

##### Study aim

Comparison of Ketamin/Propofol (Ketofol) and Etomidate /Fentanyl (Etofen) combinations for procedural sedation and analgesia of anterior shoulder dislocation reduction in Emergency Department

##### Design

A clinical trial with two parallel groups of Ketofol and Etofen, single-blind, randomized, phase 2 on 46 patients. The patients will be randomly assigned to one of the Ketofol or Etofen groups. Randomization is done using a table of random numbers and by the block randomization method.

##### Settings and conduct

This study is conducted on patients who referred to the emergency department of Shahid Bahonar Hospital in Kerman. The patients will be randomly assigned to one of the Ketofol or Etofen groups. According to the PSAs protocol, Ketofol with a dose of 0.75 mg/kg IV bolus of ketamine and propofol, etofen with a dose of 0.15 mg/kg IV bolus of etomidate and 0.15 µg/kg of fentanyl are given as starting doses. A repeat dose of 0.375 mg/kg ketamine and propofol every 3 minutes and 0.1 mg/kg etomidate every 2 minutes is given until adequate sedation is achieved.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults between 18 and 50 years old with anterior shoulder dislocation  
Exclusion criteria: History of allergy to any of the drugs, underlying cardiovascular disease, lung diseases and nervous system diseases, history of current drug or stimulant abuse now or in the last month, associated fracture, neurovascular symptoms, patient dissatisfaction, associated diseases

##### Intervention groups

According to the PSAs protocol, bolus of ketamine and propofol for Ketofol Group, bolus of etomidate and

fentanyl for Etofen group are given as sedation.

##### Main outcome variables

Pain score; number of attempts for reduction ; length of stay in the emergency; Drug side effects;

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220824055790N1**

Registration date: **2022-09-13, 1401/06/22**

Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**

Update count: **0**

##### Registration date

2022-09-13, 1401/06/22

##### Registrant information

##### Name

Seyed Mojtaba Habibi Khorasani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3244 3126

##### Email address

mojista.1375@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-23, 1401/08/01

##### Expected recruitment end date

2023-03-20, 1401/12/29

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of Ketamin/Propofol (Ketofol) and Etomidate /Fentanyl (Etofen) combinations for procedural sedation and analgesia of anterior shoulder dislocation reduction in Emergency Department: A Randomized Clinical Trial

**Public title**  
Comparison of Ketamin/Propofol (Ketofol) and Etomidate /Fentanyl (Etofen) in reduction of shoulder dislocation

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Adults between 18 and 50 years old Anterior shoulder dislocation  
**Exclusion criteria:**  
History of allergy to any of the drugs (ketamine, propofol, etomidate, fentanyl) underlying cardiovascular disease lung diseases nervous system diseases (central or peripheral) history of current drug or stimulant abuse now or in the last month associated fracture neurovascular symptoms patient dissatisfaction associated diseases

**Age**  
From **18 years** old to **50 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **46**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The patients will be randomly assigned to one of the Ketofol or Etofen groups. Randomization is done using a table of random numbers and by the block randomization method and in blocks of 5 people. In this way, a number is blindly selected from the table of random numbers for each position, and the two digits on the right side of it, if they are between 1 and 46, will be assigned to that position. Each of the blocks of 5 people is assigned to one group (Ketofol or Etofen). The odd blocks belong to the Ketofol group and the even blocks belong to the Etofen group. Block positions are numbered (1 to 46). For example, the first case that is randomly assigned to Ketofol group will enter the number one position of the first block (the block related to Ketofol) and this process will be done until the positions are filled and the number of samples in the two groups will be equal. .

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**  
Ketamin and Fentanyl drugs are colorless and have no difference in color, and the patient does not know which compound is being injected. Propofol is milky. Etomidate is available in two milky and colorless forms. A milky etomidate is used for the study to be similar to Propofol. Therefore, in each of the study groups, a colorless compound + a milky compound is used, and the patient is unaware of the type of drug.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**  
1  
**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Kerman Medical University  
**Street address**  
University of Medical Sciences, The beginning of Haft Bagh Alavi axis, Kerman  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7616913555  
**Approval date**  
2022-07-31, 1401/05/09  
**Ethics committee reference number**  
IR.KMU.AH.REC.1401.081

## Health conditions studied

1  
**Description of health condition studied**  
Anterior Shoulder Dislocation  
**ICD-10 code**  
S43.0  
**ICD-10 code description**  
Subluxation and dislocation of shoulder joint

## Primary outcomes

1  
**Description**  
Pain score: using numerical rating scale  
**Timepoint**  
During Reduction  
**Method of measurement**  
Ask the patient: Score from 1 to 10

## 2

### **Description**

Number of reduction attempts until reduction succeeds.

### **Timepoint**

During study until reduction succeeds.

### **Method of measurement**

-

## 3

### **Description**

Length of stay in the emergency room: the time between the patient's admission to the emergency room and discharge

### **Timepoint**

After discharge

### **Method of measurement**

View the patient file

## 4

### **Description**

Drug side effects: bradycardia, respiratory depression, hypotension

### **Timepoint**

During Study

### **Method of measurement**

Based on the form of drug side effects

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

Intervention group: According to the PSAs protocol, Ketofol with a dose of 0.75 mg/kg IV bolus of ketamine and propofol are given as starting doses. A repeat dose of 0.375 mg/kg ketamine and propofol every 3 minutes is given until adequate sedation is achieved. The goal of sedation in this study is to reach the patient's level of moderate sedation. The patient is apparently unconscious, but reacts with skin irritation. After the patient reaches the appropriate level of sedation, the emergency physician performs the sedation using the Liddle Meyer maneuver. And in case of failure, the same maneuver is repeated once more, and if it is still not successful, the next maneuver is traction. After successful reduction, the pain score, the number of reduction attempts, and the length of stay in the emergency room are measured.

### **Category**

Treatment - Drugs

## 2

### **Description**

Intervention group: According to the PSAs protocol, Etofen with a dose of 0.15 mg/kg IV bolus of etomidate

and 0.15 µg/kg of fentanyl are given as starting doses. A repeat dose of 0.1 mg/kg etomidate every 2 minutes is given until adequate sedation is achieved. The goal of sedation in this study is to reach the patient's level of moderate sedation. The patient is apparently unconscious, but reacts with skin irritation. After the patient reaches the appropriate level of sedation, the emergency physician performs the sedation using the Liddle Meyer maneuver. And in case of failure, the same maneuver is repeated once more, and if it is still not successful, the next maneuver is traction. After successful reduction, the pain score, the number of reduction attempts, and the length of stay in the emergency room are measured.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Shahid Bahonar Hospital

#### **Full name of responsible person**

Masoumeh Nazemi Rafei

#### **Street address**

Shahid Bahonar Hospital, Gharani St

#### **City**

Kerman

#### **Province**

Kerman

#### **Postal code**

7613747181

#### **Phone**

+98 34 3223 5011

#### **Email**

mojista.1375@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Kerman University of Medical Sciences

#### **Full name of responsible person**

Reza Malekpour Afshar

#### **Street address**

Vice Chancellor of Research and Technology, Ebn-e-Sina St. ,Jahad Blvd.

#### **City**

Kerman

#### **Province**

Kerman

#### **Postal code**

7619813159

#### **Phone**

+98 34 3226 3719

#### **Email**

vcr@kmu.ac.ir

#### **Grant name**

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

Yes

**Title of funding source**  
Kerman 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**  
Kerman University of Medical Sciences

**Full name of responsible person**  
Seyed Mojtaba Habibi Khorasani

**Position**  
Medical Student (Intern)

**Latest degree**  
A Level or less

**Other areas of specialty/work**  
General Practitioner

**Street address**  
Shahid Bahonar Hospital

**City**  
Kerman

**Province**  
Kerman

**Postal code**  
7613747181

**Phone**  
+98 34 3223 5011

**Email**  
mojista.1375@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences

**Full name of responsible person**  
Masoumeh Nazemi Rafei

**Position**  
Assistant Professor

**Latest degree**  
Specialist

**Other areas of specialty/work**  
Emergency Medicine

**Street address**  
Shahid Bahonar Hospital

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Kerman

### Province

Kerman

### Postal code

7613747181

### Phone

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m\_nazemi\_r@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences

**Full name of responsible person**  
Seyed Mojtaba Habibi Khorasani

**Position**  
Medical Student (Intern)

**Latest degree**  
A Level or less

**Other areas of specialty/work**  
General Practitioner

**Street address**  
Shahid Bahonar Hospital

**City**  
Kerman

**Province**  
Kerman

**Postal code**  
7613747181

**Phone**  
+98 34 3223 5011

**Email**  
mojista.1375@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is 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

### Title and more details about the data/document

Measured variables are available after unidentifiable individuals.

### When the data will become available and for how long

Up to one year after publish results.

**To whom data/document is available**

All people in the research centers.

**Under which criteria data/document could be used**

Allowed for any use.

**From where data/document is obtainable**

Seyed Mojtaba Habibi Khorasani

mojista.1375@gmail.com

**What processes are involved for a request to access data/document**

After contacting and knowing the identity of the person, information will be provided to them.

**Comments**