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 commitee 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
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Kerman
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7613747181
Phone
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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
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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

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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

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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

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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