

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of ketamine /propofol Versus ketamine/Thiopental in Procedural Sedational analgesia for Reduction of Anterior Shoulder Dislocation

Protocol summary

Study aim

Comparison of ketamine, propofol Versus ketamine,Thiopental in Procedural Sedational analgesia for Reduction of Anterior Shoulder Dislocation

Design

Randomized clinical trial with two comparative groups, double-blind, simple individual randomization from Random.org, on 90 patients

Settings and conduct

Patients with anterior shoulder dislocation referred to the emergency department of Shahid Sadoughi and Rahnemoun hospitals in Yazd After being diagnosed by a physician, patients are admitted to the study according to the inclusion and exclusion criteria and after initial measures, they are divided into two groups; Group A ketamine, propofol and group B ketamine, thiopental. Reduction occurs when proper sedation is established. Any side effects are considered and appropriate treatment is taken. The person performing the reduction and the patient themselves are not aware of the type of medication; For this purpose, the syringe containing the drug is covered in such a way that the color of the drug is not clear.

Participants/Inclusion and exclusion criteria

Patients aged 18-64 years, those who do not require reduction in the operating room, healthy patients without previous disease, and those with mild systemic disease without functional limitations according to the American Society of Anesthesiologist classification (individuals 1 and 2) and Those who have been (Nil Per Os) NPOs or consumed fluids in the last 3 hours are included in the study. Patients with any contraindications are excluded.

Intervention groups

After injection of ketorolac and midazolam to all patients, they divide randomly into two groups : in group A, ketamine, propofol and in group B, ketamine, thiopental.

Main outcome variables

time to proper sedation, discharge time, The duration of the effect of the drug ,times require additional dose of drug, pain before and during reduction, any side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200809048341N1**

Registration date: **2020-11-23, 1399/09/03**

Registration timing: **prospective**

Last update: **2020-11-23, 1399/09/03**

Update count: **0**

Registration date

2020-11-23, 1399/09/03

Registrant information

Name

Soheila Azimi Aabarghouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3828 2682

Email address

s.azimi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-28, 1399/09/08

Expected recruitment end date

2021-02-26, 1399/12/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ketamine /propofol Versus ketamine/Thiopental in Procedural Sedational analgesia for Reduction of Anterior Shoulder Dislocation

Public title

Comparison of ketamine /propofol Versus ketamine/Thiopental in Procedural Sedational analgesia for Reduction of Anterior Shoulder Dislocation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy patients without previous disease and those with mild systemic disease without functional limitations according to the American Society of Anesthesiologist classification (individuals 1 and 2) Those who have been NPOs (Nil Per Os) or consumed fluids in the last 3 hours Those that do not need to be reduced in the operating room. Age 18 to 64 years

Exclusion criteria:

Any contraindications including asthma and COPD(chronic obstructive pulmonary disease), systolic blood pressure below 90 or above 180, ischemic heart disease or heart failure, any symptoms in favor of increased intracranial pressure, glaucoma, psychosis and use of any psychotropic substances, acute or chronic alcoholism, liver or kidney failure, Allergies to any of the drugs studied or eggs or soy, people addicted to drugs, taking any sedatives or anesthetics before going to the emergency room, obstructive sleep apnea syndrome, maxillofacial malformations that block the airway, Pregnancy, dislocations lasting more than 24 hours, multiple trauma or hemodynamic instability, history of uncontrollable seizures, and patients who do not wish to participate in the study

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization: Based on a random sequence of numbers from Random.org, a table will be prepared, with the first forty-five consecutive numbers in Group A and the next forty-five consecutive numbers in Group B. These numbers will be assigned to each patient in order of referral.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person performing the reduction and the patient themselves do not know the type of medicine; For this purpose, the syringe containing the drug is covered in such a way that the color of the drug is not clear

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of School of Medicine _ Shahid Sadoughi University of Medical Sciences

Street address

Central building of Shahid Sadoughi University of Medical Sciences, Bamonar Square, Yazd

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Yazd

Postal code

89416978477

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.021

Health conditions studied**1****Description of health condition studied**

Procedural Sedational analgesia for Reduction of Anterior Shoulder Dislocation

ICD-10 code

S43.0

ICD-10 code description

Subluxation and dislocation of shoulder joint

Primary outcomes**1****Description**

Time to appropriate sedation

Timepoint

3 minutes after the last drug injection

Method of measurement

physical examination

2

Description

The duration of the effect of the drug

Timepoint

15 minutes after drug injection

Method of measurement

Physical examination

3

Description

Discharge time

Timepoint

15 minutes after drug infection

Method of measurement

Physical examination

4

Description

The pain before reduction

Timepoint

before starting reduction

Method of measurement

By the visual analog scale

5

Description

Need to additional doses of medication

Timepoint

3 minutes after the last injection

Method of measurement

Physical examination

6

Description

Incidence of any side effects

Timepoint

Before injecting the drug and every 5 minutes

Method of measurement

Physical examination and vital signs

7

Description

Pain during reduction

Timepoint

During reduction

Method of measurement

By the facial pain scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: First, we inject 30 mg of ketorolac

intravenously in all patients for 30 minutes 15 minutes before prescribing other drugs. We then inject 1 mg of midazolam intravenously into all patients. Then from the combination of ketamine / propofol (ketamine 1 mg per kg body weight (maximum 50 mg) and propofol 1 mg per kg body weight (maximum 50 mg) intravenously and slowly for 30-60 seconds) Used. If sedation does not occur in this group within 3 minutes, half the dose of the first medication is repeated. If, after injecting the initial dose, after receiving two and a half doses of the drug, proper sedation does not occur or the reduction is not successful, sedation is considered a failure and orthopedic consultation is requested. Appropriate sedation is determined by the RASS score (Richmond Agitation and Sedation Scale); We start reduction when the patient has a RASS score of -4. After sedation, reduction is performed by Liddell Meyer method and Milch alternative method is considered. In case of nausea, vomiting of ondansetron at a dose of 4 mg and in case of hypoxia, apnea or spasm, respectively, head tilt chin lift, oral airway and ambobag breathing, and if none of them were effective, intubation should be used.

Category

Treatment - Drugs

2

Description

Intervention group 2: First, all patients are injected with 30 mg of intravenous ketorolac within 30 seconds 15 minutes before prescribing other drugs. One mg of midazolam is then injected intravenously into all patients. The thiopental / ketamine combination is then used (ketamine 1 mg per kg body weight (maximum 50 mg) and thiopental 2 mg per kg body weight (maximum 100 mg) intravenously and slowly Within 30-60 seconds). If sedation does not occur in this group within 3 minutes, half the dose of the first medication is repeated. If proper sedation does not occur after injecting the initial dose after receiving two half doses, or the reduction is not successful, failure in sedation is considered and orthopedic consultation is requested. Appropriate sedation is determined by the RASS score (Richmond Agitation and Sedation Scale): We start reduction when the patient has a RASS score to -4. After sedation, reduction is performed by Liddell Meyer method and Milch alternative method is considered. In case of nausea, vomiting of ondansetron at a dose of 4 mg and in case of hypoxia, apnea or , spasm, respectively, head tilt chin lift, oral airway and ambobag breathing, and if none of them were effective, intubation should be used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital

Full name of responsible person

Soheila Azimi Abarghouei
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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Yazd 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
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Position

Medical student

Latest degree

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Other areas of specialty/work

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Taft

Province

Yazd

Postal code

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