

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Comparison of different dosage of Ketofol for Procedural Sedation and Analgesia in the Emergency Department :a Randomized,Prospective,Double-Blind Trial

Protocol summary

Summary

Nowadays, sedative or dissociative agents are administered with or without analgesics to reduce pain and increase ease of procedure performance. (1) Objectives: In this study, we aim to compare the different dosage of ketofol for efficacy and adverse events in emergency procedural sedation. (2) Design: According to a random-number table, patients are randomized to four groups of different dosage of ketofol. Group A: infusion mixture in 1:1 ratio, 2:1 ratio (group B), 3 : 1 ratio (Group C), 4 :1 ratio (Group D). (3) Setting and conduct : In this double-blind study , opaque syringes are administered for blinding. patients will be sedated to reach Ramsay sedation score of 3 or 4. (4) Participants including major eligibility criteria: Patients 14 - 65 years with American society of anesthesiology (ASA) class I - II. So that , Patients with hemodynamic instability or uncontrolled systemic, cardiac, respiratory, neurologic disorders would be excluded. Also, Allergy to soya or egg and patients who do not fill informed consent are excluded from the study. (5) Intervention: After injection different dosage of ketofol , Ramsay sedation score will be assessed and in score below 3 , additional half dose will be applied to reach the appropriate sedation depth. (6) Main outcome measures (Variables) : Severity of pain, Patients and Practitioners satisfaction , recovery time and side effects are measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111825121N1**
Registration date: **2016-04-30, 1395/02/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-30, 1395/02/11

Registrant information

Name

Majid Ghodsipour

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research ,Iran University of Medical Sciences

Expected recruitment start date

2015-12-15, 1394/09/24

Expected recruitment end date

2016-04-19, 1395/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of different dosage of Ketofol for Procedural Sedation and Analgesia in the Emergency Department :a Randomized,Prospective,Double-Blind Trial

Public title

The Comparison of different dosage of ketamine - propofol (ketofol) for Procedural Sedation and Analgesia for Orthopedic injuries in Rasoul-Akram ,Hafte-Tir and Firouzgar Emergency Department:a Randomized,Prospective,Double-Blind Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient should be candidate for procedural sedation in ED;Patient should be in age range of 14 and 65 years;Patient should be with of 1 or 2 in physical status in American society anesthesiologist classification. Exclusion criteria : Pregnancy;Patients who have history of cardiovascular disease; Moderate to severe asthma attack; Present Pneumonia; Uncontrolled diabetes mellitus; Sepsis; Neurologic /Psychiatric disease:Using neurologic /psychiatric drugs; Moderate to severe obesity; cardiac; renal; liver; pulmonary insufficiency; Allergy to ketamine; propofol; soya; egg; Multiple trauma; Patients that do not fill consent form.

Age

From **14 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **256**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

ندارد

Secondary trial Id

ندارد

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat freeway, next to Milad tower

City

Tehran

Postal code

Approval date

2015-12-14, 1394/09/23

Ethics committee reference number

9211307022

Health conditions studied

1

Description of health condition studied

Dislocation of shoulder joint

ICD-10 code

S43.0

ICD-10 code description

Dislocation of shoulder joint

2

Description of health condition studied

Dislocation of elbow

ICD-10 code

S53.1

ICD-10 code description

Dislocation of elbow

3

Description of health condition studied

Dislocation of ankle joint

ICD-10 code

S93.0

ICD-10 code description

Dislocation of ankle joint

4

Description of health condition studied

Dislocation of hip

ICD-10 code

S73.0

ICD-10 code description

Dislocation of hip

5

Description of health condition studied

Multiple fracture of femor

ICD-10 code

S72.7

ICD-10 code description

Multiple fracture of femor

6

Description of health condition studied

Multiple fracture of lower leg

ICD-10 code

S82.3
ICD-10 code description
Multiple fracture of lower leg

7

Description of health condition studied

Multiple fracture of forearm

ICD-10 code

S52.7

ICD-10 code description

Multiple fracture of forearm

Primary outcomes

1

Description

Severity of Pain

Timepoint

Before and after procedure

Method of measurement

Visual analog scale

2

Description

Recovery time

Timepoint

From last drug prescription up to get needed criteria to leave the recovery

Method of measurement

Base on minute

3

Description

Sedation time

Timepoint

From first dose drug prescription up to get needed criteria to leave the recovery

Method of measurement

Base on minute

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before and during of procedure,during recovery and complete conscious time

Method of measurement

Checking blood pressure (non invasive)

2

Description

Heart rate

Timepoint

Before and during of procedure,during recovery and

complete conscious time

Method of measurement

Checking the pulse for one minute

3

Description

Respiratory rate

Timepoint

Before and during of procedure,during recovery and complete conscious time

Method of measurement

Checking the RR for one minute

4

Description

Arterial oxygen saturation

Timepoint

Before and during of procedure,during recovery and complete conscious time

Method of measurement

Pulse oximetry monitoring

5

Description

Side effects of prescribed drugs

Timepoint

Before,during and after procedure

Method of measurement

Observation

6

Description

Patient's satisfaction

Timepoint

After procedure

Method of measurement

Base on Likert scale

7

Description

Practitioner's satisfaction

Timepoint

After procedure

Method of measurement

Base on Likert scale

Intervention groups

1

Description

Group A: A single dose of Propofol , 1 mg/kg ,IV as well as Ketamine 1 mg/kg , IV, 3 minute before the procedure .The next doses will be administered with half dose, or other sedative drugs ,if needed.

Category

Treatment - Drugs

2

Description

Group B: A single dose of Propofol , 1 mg/kg ,IV , plus Ketamine 0.5 mg/kg ,IV , 3 minute before the procedure.The next doses will be administered with half dose ,or other sedative drugs,if needed.

Category

Treatment - Drugs

3

Description

Group C: A single dose of Propofol , 1 mg/kg , IV , plus Ketamine 0.33 mg/kg ,IV , 3 minutes before the procedure.The next doses will be administered with half dose or other sedative drugs,if needed.

Category

Treatment - Drugs

4

Description

Group G: A single dose of Propofol , 1 mg/kg , IV , plus Ketamine , 0.25 mg/kg , IV, 3 minute before the procedure.The next doses will be administered with half dose,or other sedative drugs,if needed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul -Akram Hospital

Full name of responsible person

Dr. Saeed Abbasi

Street address

Rasoul-Akram Hospital, Niyayesh st. , Sattarkhan st.

City

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2

Recruitment center

Name of recruitment center

Haft-e-Tir Hospital

Full name of responsible person

Dr. Saeed Abbasi

Street address

Emam Khomeini Blvd , Shahr-e-Rey

City

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3

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Dr. Mahdi Rezai

Street address

Beh Afarin St, Karim Khan Zand Blvd, Valiasr Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr.Naserbakht

Street address

Iran University of Medical sciences, Hemmat freeway, next to Milad tower

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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

Vice chancellor for research, Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Saeed Abbasi

Position

Associate Professor

Other areas of specialty/work

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Web page address

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