

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Ketofol versus midazolam/fentanyl for Procedural Sedation and Analgesia in the Emergency Department: a Randomized, Prospective, Double-Blind Trial

Protocol summary

Summary

The objective of this randomized prospective, double-blind trial is to investigate Ketofol versus midazolam/fentanyl for procedural sedation and analgesia in the emergency department. Two set of syringes containing the drug dosage required for each 10 kg body weight were prepared by a certified anesthesiologist who did not participate in the collection of data. Ketofol syringes prepared as a 1:1 mixture of ketamine (7.5 mg) and propofol (7.5 mg) was used in group Ketofol (KF) (n = 31), and midazolam 0.4 mg + fentanyl 20 µg, in midazolam/fentanyl group (MF; n = 31). All syringes were covered with aluminum foil and were prepared to look the same. The study drugs with aforementioned dosage were given slowly over 1 minute as an initial dosage. Sedation endpoint was the comfort of the patients, with a variable degree of sedation allowing safe execution of the procedure without any pain suffering. If the patient exhibited grimacing and/or extremity movement requiring restraint, the procedure was withheld. Additional drug was then administered again in half of the last used dosage until little or no patient movement and/or grimacing occurred with the advancement of the procedure. Patient's satisfaction, recovery time, and side effects are measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009204784N1**

Registration date: **2010-11-28, 1389/09/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-11-28, 1389/09/07

Registrant information

Name

Reza Shariat Moharari

Name of organization / entity

Sina hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 8825 6883

Email address

moharari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2008-12-30, 1387/10/10

Expected recruitment end date

2009-06-30, 1388/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ketofol versus midazolam/fentanyl for Procedural Sedation and Analgesia in the Emergency Department: a Randomized, Prospective, Double-Blind Trial

Public title

Ketofol versus midazolam/fentanyl for Procedural Sedation and Analgesia in the Emergency Department: a Randomized, Prospective, Double-Blind Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients requiring PSA for mainly orthopedic procedures in the ED Exclusion criteria: American Society of Anesthesia (ASA) physical status \geq 3; a history of adverse reaction to Ketamine, Propofol, Midazolam, Fentanyl or egg; pregnancy; increased intracranial pressure; multiple trauma and psychiatric diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 31

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Imam khomeini Hospital

City

Tehran

Postal code

Approval date

2007-04-30, 1386/02/10

Ethics committee reference number

4276 253741/س

Health conditions studied

1

Description of health condition studied

orthopedic procedures in the ED

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sedation

Timepoint

before and after procedure

Method of measurement

Ramsay Sedation Score

2

Description

Severity of Pain

Timepoint

before and after procedure

Method of measurement

VAS

Secondary outcomes

1

Description

Blood pressure

Timepoint

before and after procedure

Method of measurement

checking blood pressure (non invasive)

2

Description

practitioner's satisfaction.

Timepoint

after the procedure

Method of measurement

Physician's satisfaction ratings were recorded on a Visual Analog Scale (VAS), with 0= "very unsatisfied" and 10 = "completely satisfied". Pain intensity was assessed by using a 10-cm VAS, with 0 = "no pain" and 10 = "worst possible pain."

3

Description

Arterial oxygen saturation

Timepoint

before and after procedure

Method of measurement

pulse oximetry monitoring

4

Description

Heart rate

Timepoint

before and after procedure

Method of measurement

checking the pulse for one minute

5

Description

side effects of prescribed drugs

Timepoint

before, during and after procedure

Method of measurement

observation

Intervention groups

1

Description

A single dose of Midazolam, 0.03mg/kg, IV as well as Phentanyl, 2 microgram/kg, IV, 3 minutes before the procedure. The next doses will be administered with half dose, if needed

Category

Treatment - Drugs

2

Description

A single dose of Propofol, 1mg/kg, IV as well as Ketamine 1mg/kg, 2 microgram/kg, IV, 1.5 minutes before the procedure. The next doses will be administered with half dose, if needed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency Department of Imam Hospital

Full name of responsible person

Reza Shariat Moharari

Street address

Anesthesiology Department, Sina hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotouhi

Street address

Keshavarz Blvd., Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Reza Shariat Moharari

Position

Associate Professor

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

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Reza Shariat Moharari

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Person responsible for updating data

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Full name of responsible person

Reza Shariat Moharari

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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