

# 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

Anesthesiology Department, Sina Hospital,

#### City

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#### Postal code

#### Phone

+98 911 331 2758

#### Fax

#### Email

moharari@sina.tums.ac.ir

#### Web page address

## Person responsible for scientific 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

Sina hospital, Imam Khomeini Ave., Tehran

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## Person responsible for updating data

### Contact

**Name of organization / entity**

**Full name of responsible person**

Reza Shariat Moharari

**Position**

**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

**Fax**

**Email**

moharari@sina.tums.ac.ir

**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*