

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparison of Fentofol with Ketofol to achieve the Aldret score of 12 in painful procedures in the emergency department

#### Protocol summary

Registration timing: **prospective**

#### Summary

**Objectives:** To compare Fentofol (Fentanyl+Propofol) with Ketofol (Ketamine+ Propofol) for performing painful procedures in the emergency department regarding achievement of Aldret score of 12 (which indicates that the patient can be transferred out of the cardiac monitoring area safely). **Inclusion criteria:** All patients over 16 years of age for whom a painful procedure needs to be performed in the emergency department will be included in the study. **Exclusion criteria:** presence of any co-morbidity (ASA score more than 1); procedure needs to be done in the operating room; Spo2 less than 92%; systolic blood pressure less than 100mmg; GCS (Glasgow coma scale) score less than 15. **Study population:** A total of 192 patients will be enrolled in the study by convenience sampling. Patients will be randomized using simple randomization to Ketofol or Fentofol groups. **Intervention:** depending of the study group, Fentanyl (1microgram/Kg by intravenous slow injection)+ propofol (1mg/Kg by intravenous slow injection) or Ketamine (1 mg/Kg by intravenous slow injection)+ propofol will be administered under standard procedural sedation condition. The dose may be repeated at the discretion of the physician in charge of the patient to perform the procedure safely and without marked pain or resistance by the patient. The patient and the investigator are blinded to the administered drug combination. After the end of the procedure, the Aldret score will be calculated each minute until the patient reaches the score of 12; this is the point when the time measurement stops. **Primary outcome:** Time to achieve the Aldret score of 12 in minutes

Last update:

Update count: **0**

#### Registration date

2017-09-11, 1396/06/20

#### Registrant information

##### Name

Amirhossein Mirafzal

##### Name of organization / entity

Kerman University of Medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 1247 4638

##### Email address

mirafzal@kmu.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

investigator

#### Expected recruitment start date

2017-10-01, 1396/07/09

#### Expected recruitment end date

2018-05-01, 1397/02/11

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016050615941N4**

Registration date: **2017-09-11, 1396/06/20**

#### Scientific title

Comparison of Fentofol with Ketofol to achieve the Aldret score of 12 in painful procedures in the emergency department

#### Public title

Fentofol vs. Ketofol for painful procedures in the emergency department

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: all patients over 16 years of age for whom a painful procedure needs to be performed in the emergency department. Exclusion criteria: presence of any co-morbidity (ASA score more than 1); procedure needs to be done in the operating room; Spo2 less than 92%; systolic blood pressure less than 100mmg; GCS (Glasgow coma scale) score less than 15; patient refusal to participate

### **Age**

From **16 years** old to **75 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **192**

### **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**

Kerman University of Medical Sciences

##### **Street address**

Faculty of medicine, Kerman University of Medical Sciences

##### **City**

Kerman

##### **Postal code**

#### **Approval date**

2015-05-10, 1394/02/20

#### **Ethics committee reference number**

IR.KMU.REC.1394.220

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Painful procedures in the emergency department

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

time to achieve the Aldret score of 12

#### **Timepoint**

after the procedure ended

#### **Method of measurement**

counting minutes after the beginning of drug administration

## **Secondary outcomes**

### 1

#### **Description**

adverse reactions

#### **Timepoint**

during and after the procedure

#### **Method of measurement**

recording any adverse reactions attributable to the drugs

## **Intervention groups**

### 1

#### **Description**

Arm 1: Intervention name: Fentofol (Fentanyl+ Propofol)  
Intervention description: Fentanyl (1 microgram/Kg by slow intravenous injection) and Propofol ( 1 milligram/Kg by slow intravenous injection) are administered in separate 5 ml syringes with a number assigned to the drugs. The patients and the investigator are blinded to the drugs in the syringe. if needed, the same doses are repeated to achieve appropriate sedation and analgesia and the total dose will subsequently be calculated. After the end of the procedure, the Aldret score will be calculated each minute until the patient reaches a score of 12, at which point the time measurement ends.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Arm 2: Intervention name: Ketofol (Ketamine+ Propofol)  
Intervention description: Ketamine (1milligram/Kg by slow intravenous injection) and Propofol ( 1 milligram/Kg by slow intravenous injection) are administered in separate 5 ml syringes with a number assigned to the drugs. The patients and the investigator are blinded to the drugs in the syringe. if needed, the same doses are repeated to achieve appropriate sedation and analgesia and the total dose will subsequently be calculated. After

the end of the procedure, the Aldret score will be calculated each minute until the patient reaches a score of 12, at which point the time measurement ends.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Bahonar Academic Hospital

**Full name of responsible person**

Amirhossein Mirafzal

**Street address**

Gharani St., Bagh-e-Melli Crossway

**City**

Kerman

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahrad Tajaddini (investigator)

**Full name of responsible person**

Shahrad Tajaddini

**Street address**

Bahonar Academic Hospital, Gharani St.,

**City**

Kerman

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahrad Tajaddini (investigator)

**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**

Kerman University of Medical Sciences

**Full name of responsible person**

Amirhossein Mirafzal

**Position**

Assistant professor of emergency medicine

**Other areas of specialty/work****Street address**

Bahonar Hospital, Gharani St.,

**City**

Kerman

**Postal code****Phone**

+98 34 3223 5011

**Fax****Email**

a.mirafzal@yahoo.com- mirafzal@kmu.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kerman University of medical Sciences

**Full name of responsible person**

Shahrad Tajaddini

**Position**

Assistant professor of emergency medicine

**Other areas of specialty/work****Street address**

Bahonar Hospital, Gharani St.,

**City**

Kerman

**Postal code****Phone**

+98 34 3223 5011

**Fax****Email**

tajadinishahrad@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of medical Sciences

**Full name of responsible person**

Amirhossein Mirafzal

**Position**

Assistant professor of emergency medicine

**Other areas of specialty/work****Street address**

Bahonar Hospital, Gharani St.,

**City**

Kerman

**Postal code****Phone**

+98 34 3223 5011

**Fax****Email**

a.mirafzal@yahoo.com- mirafzal@kmu.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*