Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016050615941N4**

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

Registration timing: **prospective**

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 sceinces

Country

Iran (Islamic Republic of)

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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

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.,

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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

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

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Position

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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