Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of efficacy and adverse events of ketamine-propofol(ketofol) with ketamine alone for procedural sedation and analgesia in emergency department

Protocol summary

Summary

Objectives: Ketamine is widely used for procedural sedation and analgesia in emergency department. Hypertension, nausea and vomiting and emergence reactions are frequently adverse events of Ketamine. Propofol is known as an effective drug for sedation in painful procedures. Respiratory depression is the most frequently adverse event of this drug. Due to Propofol doesn't have analgesic effects, usually a combination of a short acting analgesic opioid is used with Propofol for procedural sedation and analgesia, which causes intensification respiratory depression in propofol. due to Ketamine is an analgesic drug, combination of these two drugs has been examined in several studies, but a number of studies with different doses and ratios of these two drugs is needed to confirm the efficacy and preference of this compound. In this study efficacy and adverse events of Ketamine and Propofol combination with Ketamine alone are compared. Design: randomized, double blind, phase 3 of trial Setting and conduct: Ketamine and Propofol combination (0.375 milligram per kilogram doses of either drug) and Ketamine alone (0.75 milligram per kilogram) Prescribed in two groups of 40 objects and adverse events record in questionnaire. Inclusion and exclusion criteria: patient should be Candidate for Procedural sedation and analgesia in emergency department, 18-60 age old, with score of 1 or 2 in physical status in American society of anesthesiologist classification and fasting at least for 3 hours. Intervention: Prescription of 0.075 milliliter per kilogram Ketofol or Ketamine Main outcome measures: Nausea or vomiting; recovery or procedural agitation; respiratory adverse events

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014053117927N1**
Registration date: **2015-06-29, 1394/04/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-29, 1394/04/08

Registrant information

Name

Javad Hajizadeh Reineh

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, Aja university of medical sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-01-14, 1393/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of efficacy and adverse events of ketamine-propofol(ketofol) with ketamine alone for procedural sedation and analgesia in emergency department

Public title
Comparison of Ketofol with Ketamine for procedural sedation and analgesia in emergency department

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patient should be Candidate for Procedural sedation and analgesia in emergency department (complicated laceration repair, abscess incision and drainage, closed joint reduction); Adult patient (should be in age range of 18 and more and 60 and less); Patient should be with score of 1 or 2 in physical status in American society of anesthesiologist classification; If it is not the urgency procedures patient should be fasting at least for 3 hours; Any other drugs except the study drugs (such as opioids or sedatives) shouldn't be prescribed to the patient prior to the study; Patient shouldn't have the Known allergy to Ketamine or any component of the formulation; Patient shouldn't have the Known allergy to Propofol or any component of the formulation (Egg and Soya); Patient shouldn't suffer from the illnesses which have high Intracranial pressure or the illnesses which having high Intracranial pressure is dangerous, such as (intracranial tumor, subdural hematoma, Head injury, Hydrocephalus); Patient shouldn't suffer from the open eye injuries and eye diseases (glaucoma, etc) in which the intraocular pressure is dangerous; Patient shouldn't suffer from Known aneurysm; Patient shouldn't have the history of co-existing psychotic disease such as schizophrenia and epilepsia; Patient shouldn't be pregnant. Exclusion criteria The patient or his attendant don't sign printed informed consent form.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
simple random sampling (the first patient in the control group, the second patient in the intervention group, the third patient in the control group and so on until the last patient)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Aja university of medical sciences

Street address
Aja university of medical sciences, Shahid Etemadzadeh St, westerly shahid Fatemi St

City
Tehran

Postal code

Approval date
2014-02-10, 1392/11/21

Ethics committee reference number
9222

Health conditions studied

1

Description of health condition studied
Dislocation of elbow

ICD-10 code
S53.1

ICD-10 code description
Dislocation of elbow

2

Description of health condition studied
Dislocation of shoulder joint

ICD-10 code
S43.0

ICD-10 code description
Dislocation of shoulder joint

3

Description of health condition studied
Dislocation of radial head

ICD-10 code
S53.0

ICD-10 code description
Dislocation of radial head

4

Description of health condition studied
Dislocation of wrist

ICD-10 code
S63.0

ICD-10 code description
Dislocation of wrist

5

Description of health condition studied
Dislocation of toe(s)
ICD-10 code
S93.1
ICD-10 code description
Dislocation of toe(s)

6

Description of health condition studied
laceration repair
ICD-10 code
ICD-10 code description

7

Description of health condition studied
Dislocation of ankle joint
ICD-10 code
S93.0
ICD-10 code description
Dislocation of ankle joint

8

Description of health condition studied
removal of pins
ICD-10 code
Z47.0
ICD-10 code description
Follow-up care involving removal of fracture plate and other internal fixation device

9

Description of health condition studied
repair of open wound of finger with damage to nail
ICD-10 code
S61.1
ICD-10 code description
Open wound of finger(s) with damage to nail

Primary outcomes

1

Description
nausea and/or vomiting
Timepoint
From drug prescription up to get needed criteria to leave the recovery
Method of measurement
The frequency of nausea and/or vomiting; record in questionnaire

2

Description
Procedural agitation
Timepoint
During the procedure to just before starting the recovery
Method of measurement
Base on physician’s judge; Patient interferes with the procedure or/and shows unusual reactions to painful manipulation despite enough doses of drug; record in questionnaire

3

Description
Recovery agitation
Timepoint
From the beginning of recovery to get required criteria to leave the recovery
Method of measurement
Base on physician’s judge; excessive excitement, arousal and agitation in the form of crying, hallucinations can be seen; record in questionnaire

4

Description
respiratory adverse events
Timepoint
From drug prescription up to get needed criteria to leave the recovery
Method of measurement
Based on Quebec criteria; record in questionnaire

Secondary outcomes

1

Description
efficacy
Timepoint
From drug prescription up to end of the procedure
Method of measurement
Efficacy in this study is defined 1) recall the events during the procedure in unpleasant way 2) patient doesn't experience the adverse events which cause unfinished procedure, permanent complication or unplanned admission to hospital.3)patient doesn't resist actively against the procedure and record in questionnaire.

2

Description
heartbeat rate
Timepoint
every minutes, 3 minutes before injection to achieve the required criterion for exiting the recovery
Method of measurement
Heartbeat rate in per minute shown by monitoring with the brand called Sa'adat; record in questionnaire

3

Description
blood pressure
Timepoint
3 minutes before injection, a minute after injection and per 4 minutes after injection to achieve the required

criterion for exiting the recovery

Method of measurement

amount of blood pressure Based on millimeters of mercury shown by monitoring with the brand called Sa'adat; record in questionnaire

4

Description

The onset of medication to achieve adequate depth of sedation

Timepoint

The start of injection to achieve a Ramsay sedation score of 5 or more

Method of measurement

The duration of sedation score 5 or more is achieved. the sedation score should be announced per minute to end of the procedure; record in questionnaire

5

Description

recovery time

Timepoint

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

Method of measurement

Base on Aldrete scale; minimum score of 8, with a minimum of 2 in respiratory and oxygen saturation; every minute; record in questionnaire

6

Description

Muscular rigidity

Timepoint

From drug prescription up to end of the procedure

Method of measurement

Base on physician’s judge; record in questionnaire

Intervention groups

1

Description

Intervention group: First the concentration of Ketamine(produce by hameln pharmaceuticals gmbh) should be diluted to 10 milligram per milliliter and then combine 5 milliliter of that with 5 milliliter of Propofol (10 milligram per milliliter produced by B Braun company) in a syringe. Sedation should start with an initial dose of .075 milliliter per kilogram Ketofol (0.375 milligram per kilogram Ketamine, 0.375 milligram per kilogram Propofol) in 30 seconds. One minute after the initial dose and per minute subsequent after that patient's level of sedation be measured according to Ramsay sedation scale. When the Ramsay sedation levels 5 or 6 achieve, the procedure will begins. If the physician diagnoses the sedation level is not properly (less than 5 Ramsay score) 0.0375 milliliter per kilogram ketofol (0.188 milligram per kilogram of either Ketamine and propofol) is prescribed and after a minute procedure will begins if the sedation level is proper. Information will record in questionnaire.

Category

Treatment - Drugs

2

Description

Control group : First the concentration of Ketamine(hameln pharmaceuticals GmbH) should be diluted to 10 milligram per milliliter. sedation is prescribed with initial dose of 0.075 milliliter per kilogram Ketamine(0.75 milligram per kilogram) in 30 seconds. One minute after the initial dose and per minute subsequent after that patient's level of sedation is measured according to Ramsay sedation scale. When the Ramsay sedation levels 5 or 6 achieve ,the procedure will begins. If the physician diagnoses the sedation level is not properly (less than 5 Ramsay score) 0.0375 milliliter per kilogram Ketamine(0.375 milligram per kilogram) is prescribed and after a minute procedure will begins if the sedation level is proper. Information will record in questionnaire.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Dr. Zia Hejripour

Street address

Hejrat Blvd., Takhti Intersection, Afsariyeh highway

City

Tehran

2

Recruitment center

Name of recruitment center

Doctor Moayeri hospital

Full name of responsible person

Dr. Gholami

Street address

The end of Mojahedin Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Aja university of medical sciences

Full name of responsible person

Dr. Ali Mohammadshahi

Street address

elite deployment office, third floor, Aja university of

medical sciences, Shahid Etemadzadeh St, westerly shahid Fatemi St

City
Tehran

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, Aja 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
Javad Hajizadeh Reineh

Position
Anesthesiologist Asistant

Other areas of specialty/work

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Other areas of specialty/work

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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