Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Compare the effects of low-dose combination of anesthetic drugs (including fentanyl, propofol, midazolam, ketamine and lidocaine) with the usual dose of propofol in creating deep sedation

Protocol summary

Summary

The aim of this study is to compare the effect of the anesthetic Low dose (including fentanyl, propofol, midazolam, ketamine and lidocaine) in deep sedation and its complications with the usual dose of propofol. The study is a single blind randomized clinical trial. In this study patients that require sedation in emergency department of Emam Hossein hospital, randomly are divided in two groups that first group is given low dose combination of anesthetic drugs including propofol in a dose of 0.5 miligram (mg) per kilogram of body weight, ketamine 0.2 to 0.25 mg per kilogram, midazolam 0.01 to 0.02 mg per kilogram, fentanyl 0.5 to 1 microgram per kilogram and lidocaine 0.5 to 1 mg per kilogram of body weight and second group is given propofol at a dose of 1 mg per kilogram and fentanyl 1 microgram per kilogram of body weight, and Its effects include the time required to create deep sedation , depth of sedation, the needed time for recovery, also effects of sedation, physician and patient satisfaction will be recorded. The total sample size is 122 patients (61 patients per group). Inclusion criteria: Patients admitted to the emergency department over 15 years to 60 years of age and they need PSA. Exclusion criteria: previous allergy to drugs used; sensitivity to egg or soy; Hemodynamic Instability; pregnancy; drug interactions; increased ICP.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112525235N1**
Registration date: **2016-11-04, 1395/08/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-11-04, 1395/08/14

Registrant information

Name

Shahram Shokrzadeh

Name of organization / entity

Shahid Beheshti University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 911 195 4119

Email address

a.amini@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Reseach of Shahid Beheshti University of Medical Science

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effects of low-dose combination of anesthetic drugs (including fentanyl, propofol, midazolam, ketamine and lidocaine) with the usual dose of propofol in creating deep sedation

Public title

Comparison of anesthetic drugs to create deep sedation.

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients admitted to the emergency department of Emam Hossein hospital over 15 years to 60 years of age and they need Procedural sedation and analgesia (PSA) Exclusion criteria: previous allergy to drugs used in the study; sensitivity to egg or soy products; Hemodynamic Instability; pregnancy; drug interactions; increased intracranial pressure (ICP)
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **122**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Patients were divided by blocked randomization method.

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Commitee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Science, Next to the Ayatollah Taleghani Hospital, Martyr Arabi Street, Yemen Street, Martyr Chamran highway, Tehran
City
Tehran
Postal code
198396-3113
Approval date
2015-02-15, 1393/11/26
Ethics committee reference number
sbmu.rec.13930717

Health conditions studied

1

Description of health condition studied
Procedural Sedation and Analgesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The needed time for recovery from deep sedation
Timepoint
Every 30 seconds since the beginning of deep sedation
Method of measurement
The interval time between induction of sedation (Ramsay score 6) and recovery (Ramsy score of 2

2

Description
The depth of sedation
Timepoint
Every 30 seconds since the beginning of sedation
Method of measurement
the depth of sedation according to the Ramsay score

3

Description
The time required to create deep sedation
Timepoint
Every 30 seconds
Method of measurement
Since the beginning of sedative drugs to achieve deep sedation (Ramsay score equal to 6)

Secondary outcomes

1

Description
Cardiac arrhythmia
Timepoint
continuously since the beginning of sedation
Method of measurement
Cardiac monitoring

2

Description
Arterial blood pressure
Timepoint
Before prescription of drugs, then every 5 minutes until

recovery time

Method of measurement

Using the sphygmomanometer

3

Description

physician and patient's satisfaction

Timepoint

after the procedure

Method of measurement

By questionnaire

4

Description

Arterial blood oxygen saturation

Timepoint

Continuously since the beginning of sedation

Method of measurement

Pulse oximetry

5

Description

Vomiting

Timepoint

since the beginning of sedation until full recovery

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Intervention group patients are given low doses of sedative drugs, including propofol in a dose of 0.5 mg per kilogram of body weight, ketamine 0.2 to 0.25 mg per kilogram of body weight, midazolam at doses of 0.01 to 0.02 mg per kilogram of body weight, fentanyl 0.5 to 1 microgram per kg of body weight and lidocaine 0.5 to 1 mg per kilogram of body weight Intravenously .

Category

Treatment - Drugs

2

Description

Control group: patients in control group are given propofol at a dose of 1 mg per kilogram and fentanyl 1 microgram per kilogram of body weight Intravenously .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein hospital, Tehran

Full name of responsible person

Shahram Shokrzadeh.MD

Street address

Emam Hossein Hospital, Shahid madani ave, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Reseach of Shahid Beheshti University of Medical Science

Full name of responsible person

Shahram Shokrzadeh

Street address

Shahid Beheshti University of Medical Science, Next to the Ayatollah Taleghani Hospital, Martyr Arabi Street, Yemen Street, Martyr Chamran highway, Tehran

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 Reseach of Shahid Beheshti University of Medical Science

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

Shahid Beheshti University of Medical Science

Full name of responsible person

Shahram Shokrzadeh.MD

Position

Resident of Emergency Medicine

Other areas of specialty/work

Street address

Emam Hossein Hospital, Shahid Madani Ave, Tehran

City

Tehran

Postal code

-

Phone

+98 21 73430

Fax

+98 21 7755 7069

Email

shahram.shokrzadeh@gmail.com

Web page address

ehmc.sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical science

Full name of responsible person

Afshin Amini . MD

Position

Asisstant Professor of Emergency Medicine

Other areas of specialty/work

Street address

Emam Hossein Hospital, Shahid Madani Ave, Tehran, Iran

City

Tehran

Postal code

-

Phone

+98 21 73430

Fax

+98 21 7755 7069

Email

a.amini@sbmu.ac.ir

Web page address

-

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Shahram Shokrzadeh.MD

Position

Resident of Emergency Medicine

Other areas of specialty/work

Street address

Emam Hossein Hospital, Shahid Madani Ave, Tehran

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Tehran

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-

Phone

+98 21 73430

Fax

+98 21 7755 7069

Email

shahram.shokrzadeh@gmail.com

Web page address

ehmc.sbmu.ac.ir

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