Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of cough frequency and duration of recovery with three anesthesia methods: "Propofol + Fentanyl", "Propofol + Fentanyl + Lidocaine" and "Propofol + Fentanyl + Lidocaine + Ketamine" in patients referred to the scoping ward

Protocol summary

Study aim
Evaluation of cough frequency and duration of recovery with three anesthesia methods: "Propofol + Fentanyl", "Propofol + Fentanyl + Lidocaine" and "Propofol + Fentanyl + Lidocaine + Ketamine" in patients referred to the scoping ward

Design
Clinical trial with 3 parallel groups of one-way blind and sample size of at least 100 people by random sampling method using black, red and white cards

Settings and conduct
The study is a single blind and patients are unaware of the type of sedation drug for scoping. Patients in each group receive the desired sedative drug and different variables are recorded in the relevant checklist after examination. Research site: The scope of the hospital is 501 AJA

Participants/Inclusion and exclusion criteria
Participants: Candidates for scoping in 501 Army Hospital in 2021 Inclusion criteria: All patients aged 18 to 70 years are candidates for Skoping. Exclusion criteria: : Age under 18 and over 70 years ASA classification 4 or 5 History of uncontrolled blood pressure History of Chronic Obstructive Pulmonary Disease (COPD) History of psychotic or neurological disorders History of seizures History of use of drugs affecting the central nervous system Pregnancy

Intervention groups
Group A includes patients in whom propofol + fentanyl has been used for sedation for scoping. Group B includes patients in whom "propofol + fentanyl + lidocaine" drugs have been used for sedation for scoping, and group C includes patients in whom "propofol + fentanyl + lidocaine + ketamine" drugs have been used for sedation for scoping. Used.

Main outcome variables
frequency of cough, recovery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200921048789N2**
Registration date: **2021-04-12, 1400/01/23**
Registration timing: **prospective**

Last update: **2021-04-12, 1400/01/23**
Update count: **0**

Registration date
2021-04-12, 1400/01/23

Registrant information

Name
Sepehr Edalat khah

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4424 2961

Email address
sepehr.edalatkhah@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of cough frequency and duration of recovery with three anesthesia methods: "Propofol + Fentanyl", "Propofol + Fentanyl + Lidocaine" and "Propofol + Fentanyl + Lidocaine + Ketamine" in patients referred to the scoping ward

Public title
Evaluation of anesthesia quality with three methods: "propofol + fentanyl " Vs "propofol + fentanyl + lidocaine" Vs "propofol + fentanyl + lidocaine + ketamine" in patients referred to the scoping ward
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients who are candidates for scoping in 501 Army Hospital in 2021
Exclusion criteria:
Age under 18 and over 70 years ASA classification 4 or 5 History of uncontrolled blood pressure History of Chronic Obstructive Pulmonary Disease (COPD) History of psychotic or neurological disorders History of seizures History of use of drugs affecting the central nervous system Pregnancy
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The sample size in this study is at least 100 patients who will be admitted to the study by block randomization method. For this purpose, the letter A is used to place patients in the group "propofol + fentanyl", the letter B is used in the group "propofol + fentanyl + lidocaine" and the letter C is used in the group "propofol + fentanyl + lidocaine + ketamine". The size of all blocks is equal and in this three-group experiment, we use 6 blocks (including two people in group A, two people in group B and two people in group C) that were obtained using random sequence generation software. Also, in order to hide the random sequence on the participants, opaque sealed envelopes sealed with random sequences (SNOSE) are used and each sequence is recorded on a card and the cards are placed in the envelopes respectively. Based on the order of entry of eligible participants in the research, the envelopes are opened in order and the assigned group of the participant is determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, patients are unaware of the type of sedation drug for scoping, but the specialist physician, treatment staff, and research team are aware of the type of drug combination that was randomly selected for the patient.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی ارتش جمهوری اسلامی ایران
Street address
Aja univercity of medical science, Etemadzadeh St., West Fatemi Ave.,
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1411718541
Approval date
2021-02-16, 1399/11/28
Ethics committee reference number
IR.AJAUMS.REC.1399.239

Health conditions studied

1

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

Primary outcomes

1

Description
Frequency of cough
Timepoint
During and after the intervention
Method of measurement
View on the patient bed

2

Description

Duration of recovery

Timepoint

After intervention

Method of measurement

View on the patient bed

Secondary outcomes

1

Description

O2 saturation

Timepoint

During and after the intervention

Method of measurement

view on the patient's bed

Intervention groups

1

Description

Intervention group: Group A includes patients in whom propofol + fentanyl has been used for sedation for scoping. Propofol-lipuro: initial dose 1mg/kg and repeat dose 0.5 mg/kg every 3-5 min and Fentanyl (Rotexmedica): 0.5 mic g/kg single dose.

Category

Treatment - Drugs

2

Description

Intervention group: Group B includes patients in whom propofol + fentanyl + lidocaine have been used for sedation for scoping. Propofol-lipuro: initial dose 1mg/kg and repeat dose 0.5 mg/kg every 3-5 min and Fentanyl(rotexmedica): 0.5 mic g/kg single dose and Lidocaine (pasteur): 1.5 mg/kg single dose.

Category

Treatment - Drugs

3

Description

Intervention group: Group C includes patients in whom propofol + fentanyl + lidocaine + ketamine have been used for sedation for scoping. Propofol(lipuro): initial dose 0.5mg/kg and repeat dose 0.25 mg/kg every 3-5 min and Fentanyl (Rotexmedica): 0.25 mic g/kg single dose and Lidocaine (pasteur): 0.75 mg/kg single dose and ketamine (Rotexmedica) 0.5 mg/kg single dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Aja 501 hospital

Full name of responsible person

Mohammadreza Rafiei

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Aja univercity of medical science, Etemadzadeh ST., West Fatemi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Saeed Soleyman Meygooni

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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

Artesh University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person
Mohammadreza rafiei
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Research data can be published at the end of the study after identifying individuals
When the data will become available and for how long
After the end of the research and publication of the article
To whom data/document is available
All researchers and physicians engaged in the field of anesthesia and intensive care
Under which criteria data/document could be used
Only for research and treatment purposes and by mentioning the names of those involved in this study
From where data/document is obtainable
By email to Dr. Mohammad Reza Rafiei at Rafiei_mohamadreza@yahoo.com
What processes are involved for a request to access data/document
After receiving the email, the applicant's request will be reviewed and if approved, the information will be sent to them
Comments