

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of sedative effect of propofol_ketamine and propofol_fentanyl in patients undergoing gastrointestinal endoscopy procedure in ahvaz emam Khomeini hospital in 1399

Protocol summary

Study aim

Comparison of sedative effect of propofol ketamine and propofol fentanyl in patients undergoing endoscopy in Imam Khomeini Hospital, Ahvaz

Design

Clinical trial, phase 3 with parallel, randomized, double-blind groups

Settings and conduct

86 patients referred to the endoscopy ward of Imam Khomeini Hospital were randomly divided into two groups. Then, after obtaining their written consent, the first group was given 0.5 mg / kg propofol with 1 mg / kg ketamine and the second group 0.5 mg / kg propofol and 1 µg/ kg fentanyl are injected and the sedation rate of these drugs is compared

Participants/Inclusion and exclusion criteria

In this study, which is performed on patients undergoing endoscopy in Imam Khomeini Hospital, all patients with an age range of 18 to 65 years will be studied, and patients with drug allergies, patients outside the age range of 18 to 65 years, patients with renal or liver failure. Other cardiovascular diseases and those who do not wish to participate in the study are excluded from the study

Intervention groups

Patients are divided into two groups and then the first group is given 0.5 mg / kg propofol with 1 mg / kg ketamine and the second group is injected with 0.5 mg / kg propofol and 1 g / kg fentanyl.

Main outcome variables

Sedation

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20200920048770N1**

Registration date: **2020-10-25, 1399/08/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-25, 1399/08/04**

Update count: **0**

Registration date

2020-10-25, 1399/08/04

Registrant information

Name

Fateme Jorfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 2462 3719

Email address

drjorfii2912@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sedative effect of propofol_ketamine and propofol_fentanyl in patients undergoing gastrointestinal

endoscopy procedure in ahvaz emam Khomeini hospital in 1399

Public title

Comparison of sedative effect of propofol_ketamine and propofol_fentanyl in endoscopy procedure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients aged 18 to 65 years who have referred to Imam Khomeini Hospital in Ahvaz for endoscopic procedure

Exclusion criteria:

Patients under 18 or over 65 years of age The patient's unwillingness to participate in the study Patients contraindicated in propofol ketamine or propofol fentanyl

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind both sides, the study of the patient's degree of sedation according to the modified Ramsey criterion during the procedure was recorded by another person who did not know the prescribed drugs to the patient

Placebo

Not used

Assignment

Parallel

Other design features

Don't have

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Ahvaz Golestan Blvd. Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2020-09-02, 1399/06/12

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.045

Health conditions studied

1

Description of health condition studied

Sedation in patients undergoing endoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

sedation

Timepoint

Before and during the intervention

Method of measurement

Ramsay sedation scale

Secondary outcomes

1

Description

Pain

Timepoint

Before and during the intervention

Method of measurement

Ambesh scor

2

Description

nausea

Timepoint

After the end of the intervention until the exit from recovery

Method of measurement

According to the visual analog scale (vas)on a ruler that is scaled from zero to ten, zero is equivalent to nausea and ten is equivalent to maximum nausea.

3

Description

Vomiting

Timepoint

After the end of the intervention until the exit from recovery

Method of measurement

Count the number of vomits

Intervention groups

1

Description

Intervethe group: first intervention group was injected with 0.5 mg / kg propofol made by Donk Kong South Node along with 1 mg / kg ketamine made by Trittau, Italy before the intervention

Category

Treatment - Drugs

2

Description

Intervention group: The second intervention group was injected with 0.5 mg / kg propofol made by donk kông company of South Korea in one dose with 1µg / kg fentanyl made by Caspian Iran company before the intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endoscopy ward of Imam Khomeini Hospital in Ahvaz

Full name of responsible person

Reza Akhondzade

Street address

Ahvaz St., Azadegan St., Imam Khomeini Medical Center, Endoscopy Department

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Rezaakh@hotmail.com

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Https://himam.ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Grant name

Three million and five hundred thousand rials

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Fateme Jorfi

Position

General Medicine Intern

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

Street address

Ahvaz, Mehr St., between Dey and Azar, Shahid Rajaei dormitory

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Person responsible for scientific inquiries

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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

Patients referred for endoscopy in Imam Khomeini Hospital were randomly divided into two groups and by injecting propofol ketamine to one group and injecting propofol fentanyl to the other group, the sedation rate of this drugs was compared.

When the data will become available and for how long

The access period will start after the end of the work and the results will be registered

To whom data/document is available

It will be accessible to everyone

Under which criteria data/document could be used

To access this data, the keywords sedative, propofol ketamine, propofol fentanyl and endoscopy are used

From where data/document is obtainable

Request an email to rezaakh@hotmail.com

What processes are involved for a request to access data/document

The request should be sent to the email of the person in charge of the study

Comments