

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison of sedation among Intravenous propofol- fentanyl and propofol- ketamine in patients underwent diagnostic colonoscopy.

Protocol summary

Summary

This study compares the effects and probable complications of two groups of mix of propofol and fentanyl with mix of propofol and ketamine (called ketofol) in sedation in patients should be undergoing diagnostic colonoscopy. Inclusion criteria are: age over 18 years ;age under 80 years;and class 1 in American Society of Anesthesiologists(ASA). Exclusion criteria are: Coronary artery disease; Neurological and psychiatric disease; Egg sensitivities. 90 patients who should be undergoing diagnostic colonoscopy will enrolled in study. Our study will be done in Emam Khomeini hospital. We describe our purpose of research study for patients then after their satisfaction we will be included them in study. Their information about age, gender, past cardiac disease, etiology of colonoscopy, drug consumption will be collect in check list form. Incidentally, patient will be divided to two groups, one will be received intra venous mix of propofol-fentanyl, dose of propofol is 0/75mg/kg and fentanyl 1ug/kg, and other group will be received intravenous mix of propofol and ketamine that named ketofol. Ketofol solution is made by mixing of 50 mg propofol and 50mg ketamine and 4 cc distilled water in a 10cc syringe. Second group will be received 0/75mg/kg ketofol. Patient sedation level will be differentiated by Ramsay sedation score and patient and physician satisfaction level will be differentiated by visual analogue scale(VAS). In both group sedation level before starting of colonoscopy should be above 5 in Ramsay scale, if not, we inject 0/3mg/kg propofol to first group and 0/3 mg/kg ketofol to second group. Median recovery time, additional dose of propofol or ketofol, additional other sedative drug, and complications like vomiting, nausea, chilling, hypoxia, and complication of emergence of ketamine will be determined and compared in both group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122711909N1**

Registration date: **2013-03-24, 1392/01/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-24, 1392/01/04

Registrant information

Name

hamed marandi

Name of organization / entity

imam khomeini hospital

Country

Iran (Islamic Republic of)

Phone

+98 44206236

Email address

h-marandi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sedation among Intravenous propofol-fentanyl and propofol- ketamine in patients underwent diagnostic colonoscopy.

Public title

Comparison of effect and probable complications of two groups of mix of propofol and fentanyl with mix of propofol and ketamin in sedation in patients should be undergoing diagnostic colonoscopy .

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:age>18years old;age<80years old; ASA1 Exclusion:age<18years old;age>80 years old;cardiovascular disease;coagulopathy;psychatric and neurologic drug user;egg sensitivity.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Room 206, 1st floor, Number1, Ghods street, Keshavarz street

City

Tehran

Postal code

Approval date

2012-07-11, 1391/04/21

Ethics committee reference number

130/665/91/3

Health conditions studied

1

Description of health condition studied

Sedation

ICD-10 code

F13

ICD-10 code description

Mental and behavioural disorders due to use of sedatives or hypnotics

Primary outcomes

1

Description

Sedation

Timepoint

Before and in colonoscopy

Method of measurement

Ramsy score sedation

Secondary outcomes

1

Description

Satisfaction of patient and physician

Timepoint

End of colonoscopy

Method of measurement

VAS (visual analouge scale)

2

Description

Recovery

Timepoint

End of colonoscopy

Method of measurement

Time

3

Description

Naueia and vomitting

Timepoint

End of colonoscopy

Method of measurement

Observation

4

Description

Chilling

Timepoint

End of colonoscopy

Method of measurement

Observation

5

Description

Hypoxia

Timepoint

lin and end of colonoscopy

Method of measurement

Pulse oximetry

6

Description

Blood pressure

Timepoint

Before colonoscopy to end of it every 3 minutes

Method of measurement

Monitoring

7

Description

Emergency complication of ketamin

Timepoint

End of colonoscopy

Method of measurement

Observation

Intervention groups

1

Description

Intervention 1:propofol0.75 mg/kg with fentanyl 1ug/kg IV

Category

Treatment - Other

2

Description

Intervention2:in a 10cc syringe,1cc ketamin+5cc propofol+4cc water,0.75mg/kg IV

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr.Rahimi

Street address

Emam Khomeini hospital, Tohid Sq,

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Shahin Akhoondzade

Street address

North door of Tehran University, Poorsina street,

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Imam Khomeini hospital

Full name of responsible person

Dr.Rahimi

Position

Professor

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