Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between dissociative conscious sedation and sedation with propofol in patients undergoing colonoscopy procedures

Protocol summary

Summary

Colonoscopy is now the most common diagnostic and therapeutic procedures in the field of GI medicine. Since this procedure is painful and causes discomfort, patients prefer to be sedated during the procedure, and also do the endoscopist. Traditional methods of sedation in which benzodiazepines and narcotics were used due to serious complications such as respiratory depression and hypotension is now under question and hypnotic drugs such as propofol are used widely, and the major side effect of this drug is apnea. Ketamine is a hypnotic agent with less respiratory side effects but may cause hallucination and loss of patient's cooperation. Dissociative conscious sedation (SQ ketamine + narcotic) is kind of sedation with less side effects which efficacy has been established in laparoscopic procedures. A unique feature of this approach is to preserve full cooperation of the patient during an invasive procedure. The purpose of this study is to compare the efficacy and adverse events of sedation with propofol and DCS in colonoscopy procedures. 48 patients are divided in to two age and sex matched groups first of which will receive propofol and fentanyl and the second will receive SQ ketamine and fentanyl. Then we will study the quality of sedation and the probable side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205079660N1**
Registration date: **2012-09-29, 1391/07/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-09-29, 1391/07/08

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-09-01, 1391/06/11

Expected recruitment end date

2013-03-01, 1391/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between dissociative conscious sedation and sedation with propofol in patients undergoing colonoscopy procedures

Public title

Comparison between sedation with subcutaneuos ketamine and sedation with propofol in patients undergoing colonoscopy procedures

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: all patients in ASA class 1 or 2 (without underlying disease or with mild underlying disease which

is well controlled by medication) undergoing colonoscopy; age between 18-60. Exclusion criteria: any uncontrolled or poor controlled underlying disease; seizure disorders; history of hypersensitivity to egg or any drug; addiction to narcotics; mental retardation or any cognitive disorder.

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical committee, Tehran univercity of medical sciences

Street address
Keshavarz blvd, Ghods ave.

City
Tehran

Postal code

Approval date
2012-05-05, 1391/02/16

Ethics committee reference number
2750/130/90/د

Health conditions studied

1

Description of health condition studied
Mental and behavioural disorders due to use of sedatives or hypnotics

ICD-10 code
F10-19

ICD-10 code description
Mental and behavioural disorders due to use of sedatives or hypnotics

Primary outcomes

1

Description
SPO2

Timepoint
Continuous

Method of measurement
pulse oxiometery

2

Description
blood pressure

Timepoint
every 5 minutes

Method of measurement
noninvasive cuff measurrment

3

Description
heart rate

Timepoint
every 5 minutes

Method of measurement
pulse counting

Secondary outcomes

1

Description
apnea

Timepoint
continuous

Method of measurement
observation

Intervention groups

1

Description
First group will receive 2microgram/kg fentanyl + propofol 50-75 mg/kg during the procedure and if needed additional fentanyl will be added up to 4 micro/kg.

Category
Treatment - Drugs

2

Description
The second group will receive 2microgram/kg fentanyl + 0.6 mg/kg SQ ketamine during the procedure and if needed additional fentanyl up to 4 micro/kg will be added. The site of SQ injection is in front of the fore arm in all patients.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomaini hospital
Full name of responsible person
Mihan Javid MD
Street address
Keshavarz blvd, Gharib aveneu
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mihan Javid
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Keshavarz Blv, Ghods Avenue
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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
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
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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