

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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

Name

Sanaz Sha`bani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3605 0354

Email address

s-shaabani@razi.tums.ac.ir

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 subcutaneous 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 university 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

2750/130/90/3

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 oximetry

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 Khomainsi 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

Street address

Keshavarz Blv, Ghods Avenue

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**

Tehran University of Medical Sciences

Full name of responsible person

Sanaz Sha`bani

Position

Resident in anesthesia and critical care

Other areas of specialty/work**Street address**

Imam Khomainsi Hsp.

City

Tehran

Postal code**Phone**

+98 21 61190

Fax**Email**

sanazshaabani@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mihan Ja`fari Javid

Position

Associated Professor

Other areas of specialty/work**Street address**

Imam Khomainsi Hsp.

City

Tehran

Postal code**Phone**

+98 21 6119 2828

Fax**Email**

mihanjavid@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Sanaz Sha`bani

Position

resident

Other areas of specialty/work**Street address**

Imam Khomainsi Hsp

City

Tehran

Postal code**Phone**

+98 21 6119 2828

Fax**Email**

sanazshaabani@yahoo.com

Web page address**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