

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Subcutaneous Dissociative Conscious Sedation (CDS) an Alternative Method for General Anesthesia in Rigid Bronchoscopy (A New Approach)

Protocol summary

2012-11-25, 1391/09/05

Summary

Predicted compromised airway is absolute indication for general anesthesia and preserving spontaneous breathing is of great importance in these patients. Rigid bronchoscopy in order to dilate the stenotic trachea needs general anesthesia by preserving spontaneous breathing. Dissociative Conscious Sedation (DCS) by employing subcutaneous ketamine plus narcotic is a new method of sedation with few side effects. The aim of this method is preserving patient's safety by applying spontaneous ventilation beside effective anesthesia and amnesia. The 48 patients are divided in to two groups each including 24 cases. Inclusion criteria is 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 is 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. The first group will receive midazolam + fentanyl as premedication and na thiopental + atracurium for induction. The second group will receive fentanyl + 0.6 mg/kg SQ ketamine+ morphine during the procedure. At the end of the study two groups will be comparing in hemodynamic parameters and side effects.

Registrant information

Name

Sanaz Sha`bani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-03-01, 1390/12/11

Expected recruitment end date

2013-03-01, 1391/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210199660N2**

Registration date: **2012-11-25, 1391/09/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Scientific title

Subcutaneous Dissociative Conscious Sedation (CDS) an Alternative Method for General Anesthesia in Rigid Bronchoscopy (A New Approach)

Public title

Subcutaneous Dissociative Conscious Sedation (CDS) an Alternative Method for General Anesthesia in Rigid Bronchoscopy

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)**

Single 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**

2010-08-20, 1389/05/29

Ethics committee reference number

62086

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**

The first group will resieve 1mg midazolam + 2 micro/kg fentanyl as premedication and 5mg/kg na thiopental + 0.6 mg/kg atracurium for induction.

Category

Treatment - Drugs

2**Description**

The second group will receive 1mg midazolam + 2microgram/kg fentanyl + 0.6 mg/kg SQ ketamine + 0.1mg/kg morphine during the procedure. The site of SQ injection is in front of the fore arm in all patients. Drug

administration and monitorings all are done by a resident of anesthesiology in train. and all the intubations will be perform by a single person who is a resident of anesthesiology in train.

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. Shahin Akhondzadeh

Street address

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****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**

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

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Full name of responsible person

Dr. Mihan Ja`fari Javid

Position

Associated Professor

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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**

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City

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Email

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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