

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### **A comparison between general anesthesia versus dissociative conscious sedation\_ subcutaneous ketamin+ intravenous narcotics\_ in hemodynamic responses to endobronchial intubation in imam khomains hospital, on 1391**

#### **Protocol summary**

##### **Summary**

Laryngoscopy and endobronchial intubation leads to increase in serum catecholamine level which results in hemodynamic responses such as hypertension and tachycardia. The difference between endobronchial intubation and endotracheal intubation is the depth of tube insertion in the trachea and the degree of stress responses. Dissociative Conscious Sedation (DCS) by employing subcutaneous ketamine and narcotic is a new approach, safety and usefulness of which is been proven in other invasive procedures. The aim of this study is to study the usefulness of this method in endobronchial intubation. The 48 patients are divided in to two groups each including 24 cases. Inclusion criteria was 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 was 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.

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT201210209660N3**  
Registration date: **2012-11-25, 1391/09/05**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### **Registration date**

2012-11-25, 1391/09/05

##### **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**

2011-12-22, 1390/10/01

##### **Expected recruitment end date**

2012-12-21, 1391/10/01

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

##### **Scientific title**

A comparison between general anesthesia versus dissociative conscious sedation\_ subcutaneous ketamin+ intravenous narcotics\_ in hemodynamic responses to endobronchial intubation in imam khomains hospital, on 1391

## Public title

A comparison between general anesthesia versus dissociative conscious sedation in hemodynamic responses to endobronchial intubation.

## 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 univercity of medical sciences

##### Street address

Keshavarz blvd, Ghods ave

##### City

Tehran

##### Postal code

#### Approval date

2012-08-12, 1391/05/22

#### Ethics committee reference number

61820

## 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 measurrrment

### 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 1-3 microgram/kg fentanyl + 0.1micro/kg morphine and 1mg midazolam as premedication and 5mg/kg thiopental plus 0.6mg/kg atracurium.

#### Category

Treatment - Drugs

## 2

### Description

The second group will receive 1-3microgram/kg fentanyl + 0.1micro/kg morphine and 1mg midazolam as premedication and 0.6mg/kg subcutaneous ketamine. 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 avenue

##### 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

##### 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

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##### Phone

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sanazshaabani@yahoo.com

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## 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

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## Person responsible for updating data

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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*