

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 tracheal intubation in imam khomaini hospital, on 1391

Protocol summary

Summary

Laryngoscopy and endotracheal intubation leads to increase in serum catecholamine level which results in hemodynamic responses such as hypertension and tachycardia and providing appropriate depth of sedation is of great importance. 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 endotracheal intubation. The 48 patients are enrolled in this study. 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. Patients are divided in to two groups each including 24 cases. 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: **IRCT201210209660N4**

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

2012-02-01, 1390/11/12

Expected recruitment end date

2013-02-01, 1391/11/13

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 tracheal intubation in imam khomaini hospital, on 1391

Public title

A comparison between general anesthesia versus dissociative conscious sedation in hemodynamic responses to tracheal 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

61819

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

Tehran University of Medical Sciences

Other areas of specialty/work

Street address

Imam Khomainsi Hsp

City

Tehran

Postal code

Phone

+98 21 61190

Fax

+98 21 6119 2828

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 61190

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 61190

Fax

+98 61192828

Email

sanazshaabani@yahoo.com

Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty