Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Dissociative conscious sedation an alternative to regional airway blocks

Protocol summary

Summary

The aim of this study is evaluating “Subcutaneous Dissociative Conscious Sedation” (sDCS) as an alternative method to airway regional blocks for awake intubation. In this prospective non-randomized study, 30 patients, with predicted difficult airway (laryngeal tumors) who were scheduled for direct laryngoscopic biopsy (DLB) in whom airway regional blocks were not possible or were unsafe, were included.” Dissociative Conscious Sedation” (DCS) exerted by intravenous fentanyl 3-4ug/kg, and subcutaneous ketamine 0.7mg/kg. The tongue and pharynx were anaesthetized with lidocaine spray (4%). 8-10 minutes after subcutaneous injection of ketamine direct laryngoscopy was performed. Extra doses of fentanyl 50-100 ug was administered if the patient wasn't cooperative enough for laryngoscopy. The patients were evaluated for hemodynamic stability (heart rate and blood pressure), oxygen saturation (Spo2), patient’s cooperation (obedient to open the mouth for laryngoscopy) and the number of tries for laryngoscopy, patient’s comfort (remaining moveless), hallucination, nystagmus and salivation (need for aspiration before laryngoscopy) during the laryngoscopy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012075333N1**
Registration date: **2011-08-29, 1390/06/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-08-29, 1390/06/07

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-12-01, 1388/09/10

Expected recruitment end date

2010-02-01, 1388/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Dissociative conscious sedation an alternative to regional airway blocks

Public title

An alternative method for regional airway blocks

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: predicted difficult airway because of laryngeal tumors with impossible airway regional blocks
Exclusion criteria: history of Psychological disorders, coronary artery disease, uncontrolled hypertension, increased ICP, intracranial mass lesions, open eye injury

Age

From **40 years** old to **65 years** old

Gender

Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice Dean for Research, Faculty of medicine
Street address
Tehran University of Medical Sciences
City
Tehran
Postal code
Approval date
2011-07-30, 1390/05/08
Ethics committee reference number
13918

Health conditions studied

1

Description of health condition studied
difficult laryngoscopy and difficult intubation
ICD-10 code
Y40, y84
ICD-10 code description
Complications of medical and surgical care

Primary outcomes

1

Description
possibility of laryngoscopy
Timepoint
time of intubation
Method of measurement
successful or not successful

2

Description
possibility of fiberoptic bronchoscopy
Timepoint
time of intubation
Method of measurement
successful or not successful

3

Description
possibility of rigid bronchoscopy
Timepoint
no time point
Method of measurement
successful or not successful

4

Description
Possibility of Double lumen endobronchial intubation
Timepoint
Evaluation of possibility of endobronchial intubation
Method of measurement
possibility of procedure

Secondary outcomes

1

Description
hemodynamic changes
Timepoint
3-4 times during the procedure
Method of measurement
increased heart rate and blood pressure

2

Description
Spo2
Timepoint
continuous
Method of measurement
Pulseoximetry

3

Description
Patient's cooperation
Timepoint
during the procedure
Method of measurement
Possibility of tube insertion

Intervention groups

1

Description
1-Subcutaneous Ketamine 0.7mg/kg 2- intravenous Fentanyl 2-4 ug/kg 3- Anesthesia of the tongue, larynx

and pharynx with lidocain spray 4%

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomaini Medical center

Full name of responsible person

Mihan Jafari Javid

Street address

Tehran University of Medical Sciences

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran university of Medical Scioences

Full name of responsible person

Shahin Akhondzadeh

Street address

Vice-chancellor for Research, Faculty of Medicine, Tehran University of Medical Sciences

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 Scioences

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

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Full name of responsible person

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Associate Professor

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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