Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Effect of intranasal adminstration of dexmedetomidine in providing moderate sedation for patients undergoing ERCP ; a randomized control trial

Protocol summary

Summary

The objective of this study is evaluation of intranasal dexmedetomidine efficacy for moderate sedation induction in patients during endoscopic retrograde cholangio-pancreatography (ERCP). For this purpose, in a double blinded randomized placebo controlled clinical trial, 50 patients 18-65 years from both sex candidate for ERCP will be enrolled in the study and will be divided in two group (intervention or placebo) randomly. In intervention group, 20 min before the onset of endoscopy, 1 µg/kg of diluted dexmedetomidine in the shape of intra nasal drops and in the control group the same volume of placebo drop (normal saline) will be administer. After the entry of the patients in the endoscopy room and before the onset of procedure, midazolam and fentanyl with titrated and divided dose will be prescribed until the achievement to optimal level of sedation (score I & II Richmond scoring system). Then sedation level, total dose of midazolam & fentanyl usage and occurrence of complications such as apnea and respiratory disasters during ERCP will be recorded and compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015103011398N9**
Registration date: **2015-11-04, 1394/08/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-11-04, 1394/08/13

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Research & Technology, Iran university of medical sciences

Expected recruitment start date

2014-09-06, 1393/06/15

Expected recruitment end date

2015-03-06, 1393/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intranasal adminstration of dexmedetomidine in providing moderate sedation for patients undergoing ERCP ; a randomized control trial

Public title

Evaluation of the sedative effect of nasal dexmedetomidine in endoscopic procedures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria's are: Age 18-65 years, both sex, having

informed consent for entry to the study, ASA physical status class I-III Exclusion criteria's include: Age less than 18 and over than 65 years, ASA class over than III, history of open surgery in last week before endoscopy, chronic users of opiates & benzodiazepines, bradycardia (HR<45), systolic blood pressure less than 90 mmhg, cardiac conduction abnormality, patients using B-blockers & calcium channel blockers, patients with prolonged QT interval, active bleeding of upper or lower GI tract, patients with hemodynamic instability, pregnant patients, advanced liver insufficiency

Age

From **18 years** old to **64 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran university of medical sciences

Street address

Research deputy, 5th floor, central bilding, Iran university of medical sciences, Hemmat high way

City

Tehran

Postal code

Approval date

2013-10-15, 1392/07/23

Ethics committee reference number

9011174053

Health conditions studied

1

Description of health condition studied

Indution of sedation for endoscopy in billiary disorders

ICD-10 code

K87*

ICD-10 code description

Disorders of gallbladder, biliary tract and pancreas in diseases classified elsewhere

Primary outcomes

1

Description

Level of sedation

Timepoint

Every two min after intervention

Method of measurement

Richmond agitation sedation scale

Secondary outcomes

1

Description

Total dose of midazolam and fentanyl useage

Timepoint

End of procedure

Method of measurement

Sum of these drugs in mg/kg

Intervention groups

1

Description

Control Group: Placebo

Category

Placebo

2

Description

Nasal Dexmedetomidine 1 microgram per kg of body weight

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Somayeh Allameh

Street address

Anesthesiology department

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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7th Floor, , Department of Internal Medicine, Hazrat-E-Rasoul Hospital, Iran University of Medical Sciences, Niayesh St.,
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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
Iran 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

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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