Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Intravenous Dexmedetomidine versus Nebulised Dexmedetomidine in combination with standardised Propofol-Fentanyl-Midazolam for Procedural sedation during ERCP: a comparative evaluation of sedation efficacy

Protocol summary

Study aim
to compare the sedative efficacy of IV dexmedetomidine and nebulized dexmedetomidine when combined with standard propofol-fentanyl-midazolam during Endoscopic retrograde pancreticochalaniography

Design
Randomised, inferiority, single-blind with blinding of outcome assessor, single centre, randomised controlled trial

Settings and conduct
1. Randomly allocated into two groups using a generated random number table and concealed envelopes for sharing random allocation. 2. Dexmedetomidine administration as per group allocation will be done in the pre-procedure room and the mode of administration will not be known to the outcome assessor during the Endoscopic procedure under sedation. 5. All patients will receive midazolam(.01mg/kg) and fentanyl (1 mcg/kg) for anaesthesia induction based on ideal body weight. In both groups, anaesthesia will be maintained with continuous infusion of propofol @ 100 – 200 mcg/kg/min. If required 10 mg propofol iv bolus will be given to maintain Ramsay Sedation Scale 4

Participants/Inclusion and exclusion criteria
INCLUSION CRITERIA 1.Patients undergoing elective/emergency ERCP procedures under sedation 2. Age between 18-65 years 3. ASA grades I-III EXCLUSION CRITERIA 1. Patient refusal 2. Allergy to drug 3. Heart rate < 50 beats/min, 4. Beta-blockers 5. Shock 6. Oxygen saturation(SpO2) less than 90%, 7. Cardiomyopathy 8. Kidney or hepatic insufficiency. 9. Second or third-degree heart block, 10. Body mass index (BMI) over 36 kg/m2

Intervention groups
1. Group NEB-DEX: Nebulized dexmedetomidine 1 µg/kg diluted in normal saline (0.9%) to a volume of 5 ml 30 minutes before induction of anaesthesia and 2. Group IVDEX: IV dexmedetomidine 1 mcg/kg diluted in normal saline over 10 minutes 30 minutes before induction of anaesthesia.

Main outcome variables
Propofol consumption per unit time (mg/min)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221109056455N2**
Registration date: **2024-09-26, 1403/07/05**
Registration timing: **prospective**

Last update: **2024-09-26, 1403/07/05**
Update count: **0**

Registration date
2024-09-26, 1403/07/05

Registrant information

Name
RISHI ANAND

Name of organization / entity
TATA MAIN HOSPITAL

Country
India

Phone
+91 97165 48587

Email address
rishi.anand1@tatasteel.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-10-01, 1403/07/10

Expected recruitment end date

2025-12-31, 1404/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intravenous Dexmedetomidine versus Nebulised Dexmedetomidine in combination with standardised Propofol-Fentanyl-Midazolam for Procedural sedation during ERCP: a comparative evaluation of sedation efficacy

Public title

Intravenous Dexmedetomidine versus Nebulised Dexmedetomidine for procedural sedation during ERCP

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient undergoing procedural sedation for Endoscopic retrograde cholangio- pancreaticography ASA physical status 1- 3 AGE 18-65 Years

Exclusion criteria:

Patient refusal allergy to study drugs Heart rate less than 50/minute Patient on beta blockers Hemodynamically unstable or shock. oxygen saturation less than 95 % on room air Hepatic or renal failure Second degree or third degree heart block BMI > 36 kg/m2

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

1. A list of participants will be created in spreadsheet/excel sheet 2. Generate random numbers in next column using excel formula. 3. Sort the list based on the random numbers. 4. Assign the first half of participants to Group A and the second half to Group B. 5. Sealed envelop with serial numbers on it with allocation sealed inside, will be applied to ensure blinding and confidentiality of group assignment.

Blinding (investigator's opinion)

Single blinded

Blinding description

The administration of intravenous and nebulised Dexmedetomidine is done by different personnel neither involved in study nor procedure sedation to prevent bias. Randomly assign participants to either the intravenous or nebulised Dexmedetomidine group using a randomization table or software. Administration of medication will be done in pre op area. Anaesthesia management will be done by anaesthesiologist not related to study, using Midazolam- Fentanyl- Propofol combination. All parameters/outcome will be recorded by caregiver anaesthesiologist in proforma. Investigator will collect proforma at the end of procedure for data extraction and analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Ethics Committee Tata Main Hospital, Jamshedpur

Street address

Road C, Northern town, Bistupur, Jamshedpur

City

Jamshedpur

Postal code

831001

Approval date

2024-07-12, 1403/04/22

Ethics committee reference number

TMH/IEC/JULY/164/2024

Health conditions studied

1

Description of health condition studied

choledocholithiasis with obstruction

ICD-10 code

K80.81

ICD-10 code description

Other cholelithiasis with obstruction

Primary outcomes

1

Description

Propofol consumption per unit time

Timepoint

At the end of procedure

Method of measurement

Propofol consumption will be calculated by sum of amount consumed by infusion and rescue bolus doses of propofol. It will be divided by duration of infusion to

calculate per unit time propofol consumption.

Secondary outcomes

1

Description
Patient satisfaction score
Timepoint
at the end of procedure
Method of measurement
Patient satisfaction will be assessed using 5 point Gloucester Comfort Score

2

Description
Incidence of Adverse event(Desaturation, hypotension and bradycardia)
Timepoint
At the end of procedure
Method of measurement
Hypotension will be defined by blood pressure falling more than 20 % of baseline as measured by sphygmomanometer. Bradycardia will be counted if heart rate is less than 50 during the procedure. If saturation fall below 95 during procedure, it will be counted as desaturation episode.

Intervention groups

1

Description
Intervention group: Group NEB-DEX will receive nebulized dexmedetomidine 1 µg/kg diluted in normal saline (0.9%) to a volume of 5 ml 30 minutes prior to induction of anesthesia
Category
Treatment - Drugs

2

Description
Control group: Group IVDEX will receive iv dexmedetomidine 1 mcg/kg diluted in normal saline over 10 minutes 30 minutes prior to induction of anesthesia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
TATA MAIN HOSPITAL,JAMSHEDPUR
Full name of responsible person
ROUSHAN PATEL
Street address
Northern town, Jamshedpur
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Web page address
https://www.tatamainhospital.com/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tata Main Hospital, Jamshedpur
Full name of responsible person
Dr Rishi Anand
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Email
rishi.anand1@tatasteel.com
Web page address
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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
Tata Main Hospital, Jamshedpur
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tata Main Hospital, Jamshedpur
Full name of responsible person
Dr Rishi Anand
Position
specialist
Latest degree
Specialist
Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available