Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A Prospective, Multicenter, Randomized, Evaluation of the Efficacy of Intranasal Administration of PCDX in Providing Moderate Sedation for Patients Undergoing Gastrointestinal Endoscopic Procedures

Protocol summary

Study aim

Evaluating the Effectiveness of Intradermal Dose Administration in Providing Medium Seduction for Patients with Digestive Diseases under Gastrointestinal Endoscopy

Design

The following methods, based on the medical history and ASA classification, should be completed within 24 hours prior to the start of the GI: Checking the criteria for entering and leaving - Checking and signing informed consent - Demographics (date of birth, gender, height (cm), weight (kg), and primary diagnosis - Physical examination and history - Registration of associated drugs - Vital symptoms - Hematology and Chemistry if needed for medical reasons - pregnancy test for women of childbearing age The researcher will record vital signs (including systolic and diastolic blood pressure, temperature, pulse and respiration) after screening,

Settings and conduct

Imam Reza Hospital

Participants/Inclusion and exclusion criteria

Criteria for entering the study: Symptoms of diagnostic and endoscopic interventions of upper or lower GI procedures, or both. Man and woman at least 18 years old Otherwise, the patient is healthy or ill with systemic mild disease that is well controlled. (ASAI or II) Urinalysis or pregnancy serum in female patients at the start of the study Being able to provide informed consent is signed Exit criteria: Patients under the age of 18 years or those unable to sign an informed consent. Surgical procedures or people who have had an open surgical procedure for endoscopy within one week. Chronic opioid users or benzodiazepine for anxiety, insomnia and chronic pain. Bradycardia (heart rate <45 bpm) low blood pressure Pregnant patients

Intervention groups

The studied drug contains dexmedetomidine 100 mcg/ml (Intervention group:PCDX) or equal volume of normal saline (control group:PLCB).

Main outcome variables

Hypotension, Nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160103025821N6**
Registration date: **2019-03-14, 1397/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-14, 1397/12/23**
Update count: **0**

Registration date

2019-03-14, 1397/12/23

Registrant information

Name

Hojjat Pourfathi

Name of organization / entity

Tabriz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Prospective, Multicenter, Randomized, Evaluation of the Efficacy of Intranasal Administration of PCDX in Providing Moderate Sedation for Patients Undergoing Gastrointestinal Endoscopic Procedures

Public title
Evaluation of the Effect of Intradermal Dihydroquin Dos on Providing Sedation for Patients with Digestive Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Symptoms of diagnostic and endoscopic interventions of upper or lower GI procedures, or both Male and female at least 18 years old Otherwise, the patient is healthy or ill with mild systemic disease, which is well controlled Urinalysis or pregnancy serum in female patients at the start of the study Being able to provide informed consent is signed
Exclusion criteria:
Patients under the age of 18 years or those unable to sign an informed consent Surgical procedures or those who have had an open surgical procedure for endoscopic surgery within one week Chronic opioid use or benzodiazepine for anxiety, insomnia and chronic pain Severe hyperactivity (heart rate <45 bpm) Low blood pressure (systolic blood pressure less than 90 mmHg) Advanced heartbeats, AV blocks, second and third grade, and a branch block of the sinusoidal bacillary block that is detected during the monitoring stages in the EKG, which lasts for more than 15 seconds The chronic use of beta blockers, the calcium channel block, which may cause chronic diarrhea and life threatening bradycardia Detection of ECG 12 Lead by QT. The patient will typically not be screened for this variable Patients with upper and lower GI bleeding and patients with unstable hemodynamics Pregnant pregnant women Patients with advanced liver failure Patients who have been treated with any drug in the last 30 days Undesirable reactions to medications or predscheks in previous use History of mental disorder or use of psychiatric drugs Patients with pain in the intestinal tract Gastrectomy history There may be serious illnesses simultaneously
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **1650**
Randomization (investigator's opinion)
Randomized
Randomization description
These patients are randomly divided into two treatment groups: (825) patients in the PCDX group and (825) patients in the control group will be included in the study. Randomization is categorized by research experts and reported monthly to the central research team
Blinding (investigator's opinion)
Double blinded
Blinding description
In each clinical setting, patients are randomly assigned to one of the two treatments by the pharmacist. Gastroenterologists are registered nurses who are invited to receive anesthesia and anesthetist who may be required to manage airways, an examiner assessing the patient before discharge, and statisticians blind to the treatment used. The pharmacist randomly prescribes a drug to each patient and the patients are divided into two groups. First, in all subjects with maximum sterile precautions, it is taken in the venous route and then given to a patient randomly. Monitoring of electrocardiogram Lead II, pulse oximetry and NIBP monitoring of blood pressure. Basic signs are recorded. Excess oxygen is provided through a nasal cannula with an oxygen flow of 2 liters per minute. To prevent dryness of the nasal mucosa, excessive flow will be prevented. The nurse will prescribe the drug in the nose 20 minutes before the procedure. Both the patient (the patient and the nurse) are blinded to treatment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Research and Technology department, Tabriz University of Medical Sciences
Street address
Research Department, Daneshghah Ave, Tabriz Town
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East Azarbaijan
Postal code
5166615953
Approval date
2019-02-04, 1397/11/15
Ethics committee reference number
IR.TBZMED.REC.1397.942

Health conditions studied

1

Description of health condition studied
Effect of Intradermal Dosage Injection (PCDX)
ICD-10 code
(K50-K52)
ICD-10 code description
Diseases of the digestive system

Primary outcomes

1

Description
Low blood pressure
Timepoint
mmediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...
Method of measurement
Monitoring, Sphygmomanometer tool

2

Description
nausea
Timepoint
Immediately after the intervention, after 5 minute, after 10 minute, after 20 minute, after 40 minute, after 60 minute, after 1.5 hour, after 2 hour, after 3 hour, ...
Method of measurement
Ask the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: First, in all subjects with maximum sterile precautions, it is taken in the intravenous route and then given to a patient randomly. Monitoring of electrocardiogram Lead II, pulse oximetry and NIBP monitoring of blood pressure. Basic signs are recorded. Excess oxygen is provided through a nasal cannula with an oxygen flow of 2 liters per minute. To prevent dryness of the nasal mucosa, excessive flow will be prevented. The nurse will prescribe the drug in the nose 20 minutes before the procedure. Both the patient (the patient and the nurse) are blinded to treatment. The dose (volume) of the drug is 10 micrograms per kilogram of body weight, for example, a person will receive 100 kg of a total of 1 ml of the drug in the nose. Larger volumes can be divided into two equal doses that are prescribed in each nostril. Patients will be monitored continuously and recorded every 5 minutes with vital signs and oxygen saturation (SpO2). In this protocol, patients are monitored for moderate stenosis. After transferring patients to the endoscopy suite, a combination of midazolam, short acting benzodiazepine (initial dose of 15 µg / kg) and fentanyl citrate, a short opioid (initial dose of 0.3-0.50 µg / kg), are administered. Using the Richmond Sedation Scale (RASS), the stenting rate is considered between 1 and 2. After each dose of intravenous administration (I.V.), injector 5 ml of normal saline is injected to ensure that the drug is delivered completely. The interval between two doses will not be less than 2 minutes. Based on clinical signs and symptoms, if a suspected airway obstruction or respiratory depression is present, the nurse or gastroenterologist will stop this procedure and use airborne avionics Neck, mouthwash, and then manually ventilated with a mask to facilitate breathing. If these efforts fail, an anesthetist will help the patient with more aggressive interventions, such as laryngeal mask surgery (LMA), or intraocular tubes and positive pressure ventilation. Only clinicians using medication can do this. These providers are trained to manage emergency airways until they are contacted by an anesthetist to control airway and mechanical ventilation. Symptoms and signs for airway obstruction include: the absence of exhaled endogenous carbon dioxide, the use of minor respiratory muscles. If needed, a rescue syringe of propofol 2 mg / kg is used. In the event of hypotension, normal serum saline and vasopressor agents will be used as needed. For bradycardia, 0.5 mg of Atropine is used. After endoscopy, patients will be transferred to post-anesthetic care rooms and will be recruited by skilled nursing staff. Signs, breathing, and discomfort are constantly monitored and recorded in these units until patients have hospital clearance criteria. Modified Aldrete scoring system is commonly used in these patients to determine the clearance. Scores> 9 are considered to be cleared (Table 1). 1. Return of knowledge and activity level to preoperative level. 2. Blood pressure of about 20% of base line. 3. Respiratory tract in 20% of baseline. 4. Pain level. 4 at the reported numerical score (NRS) 5- Minimal nausea and vomiting after the fluids (PO) and vomiting to the physician 6 - The ability to walk with a low vertigo, sitting without help in your preoperative condition 7 - When a reversing factor Long-term monitoring (at least two hours) is recommended from the time of prescribing
Category
Treatment - Drugs

2

Description
The pharmacist will conduct a randomized research, and the drug will submit the study to the GI collection. The drugs are PCDX 0.1 µg / ml or normal saline (PLCB).
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Imam Reza Hospital

Full name of responsible person
Dr. Hojjat Pourfathi

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Sponsors / Funding sources

1

Sponsor

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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
Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

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
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Hojjat Pourfathi

Position
Assistant Professor in Anesthesiology

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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