Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the promethazine prescription effect on sedation, nausea reduction and quality of the upper Esophageal gastro Endoscopy

Protocol summary

Study aim

Determining the effect of promethazine prescription on sedation, reducing nausea and quality of upper esophageal and gastric endoscopy

Design

A randomized clinical trial on 22 patients. Groups include intervention and control groups. Patients will be randomly allocated to the groups using simple randomization method with random number table.

Settings and conduct

Participants will be selected from patients of Urmia Imam Khomeini endoscopy ward and will be allocated randomly to the intervention and control groups. The intervention group will be given 30 cc of promethazine syrup in 100 cc of drinking water and the control group will be given 50 glucose dissolved in 100 cc of drinking water.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 40 years, Systolic blood pressure greater than 90 and less than 130 mm Hg, peripheral blood saturation without oxygen more than 95%, no use of sleeping pills, respiratory rate between 12 to 18 times per minute، do not take any drug other than antacids ،willingness to participate in the study. Exclusion criteria: Presence of diabetes, hypertension, thyroid disease, heart disease, liver disease such as cirrhosis and hepatitis, chronic or acute lung disease, Rheumatologic disease, neurological disease and pregnancy.

Intervention groups

In the intervention group, 30 cc of promethazine syrup (1mg /cc) in 100 cc of drinking water made by Emad Darman Pars Pharmaceutical Company will be given to the patient one hour before endoscopy by someone other than the endoscopist. In the control group, 50 g of glucose dissolved in 100 cc of drinking water will be given to the patient one hour before endoscopy.

Main outcome variables

total procedure time, Patient cooperation , endoscopist satisfaction, patient satisfaction, duration of recovery , complications, patient anxiety, patient level of consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201204049599N4**
Registration date: **2021-05-15, 1400/02/25**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-15, 1400/02/25**
Update count: **0**

Registration date

2021-05-15, 1400/02/25

Registrant information

Name

Mohammad Reza Pashaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3198 8001

Email address

pashaee.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the promethazine prescription effect on sedation, nausea reduction and quality of the upper Esophageal gastro Endoscopy

Public title
Evaluation of the effect of promethazine prescription on improving endoscopy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 40 years Systolic blood pressure greater than 90 and less than 130 mm Hg Peripheral blood oxygen saturation with pulse oximetry is more than 95% Respiratory rate between 12 and 18 times per minute Do not take certain medications for a long time other than antacids.

Exclusion criteria:
pregnancy Presence of diabetes, hypertension, thyroid disease, heart disease, liver disease such as cirrhosis and hepatitis, chronic or acute lung disease, Rheumatologic disease, neurological disease

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into intervention or control groups by the randomization method with a table of random numbers. First, patients will be given a code from 01 to 22. Then a number will be randomly selected from the table and will be continued from top to bottom in the table to complete the sample size. The duplicate number will be ignored and another number from the table will be checked. Numbers 01 to 11 and 11 to 22 will be assigned to the intervention group and control group, respectively.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be double-blind. The patient and the endoscopist will be blind that which groups each patient belongs to. The amount, color, and even taste of promethazine and glucose syrup will be given equally to patients in both groups. In the intervention group, 30 cc of promethazine syrup is added into 70 cc of drinking water, one hour before the endoscopy will be given to the patient by someone other than the endoscopist. In the control group, 50 g of sugar is dissolved in 100 cc of drinking water. It will be given to the patients one hour before endoscopy after adding five cc of cherry juice (to match the color and taste of promethazine syrup).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Urmia University of Medical Sciences; Resalat boulevard

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2021-01-25, 1399/11/06

Ethics committee reference number
IR.UMSU.REC.1399.357

Health conditions studied

1

Description of health condition studied
Upper gastrointestinal endoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Total procedure time

Timepoint
During endoscopy

Method of measurement
Minute / Stopwatch

2

Description
Patient cooperation

Timepoint
During endoscopy

Method of measurement
Less than 5 retching, excellent / 6-10 times retching, good / 11-15 times retching, moderate / more than 16 retching, bad

3

Description
Endoscopist Satisfaction
Timepoint
During endoscopy
Method of measurement
Endoscopist Statement: Easy Completion / Relatively Easy Completion / Difficult Completion / Incomplete

4

Description
Patient satisfaction
Timepoint
During endoscopy
Method of measurement
Patient statement: very good / good / average / unpleasant

5

Description
Recovery time
Timepoint
After endoscopy until discharge
Method of measurement
Minute / Stopwatch

6

Description
Complications
Timepoint
From the time of drug administration until 24 hours later
Method of measurement
Through examination and self-declaration of the patient: yes / no

7

Description
Patient Anxiety
Timepoint
During endoscopy
Method of measurement
Patient statement in response to the anxiety level question: very high / high / medium / low / very low / not at all

8

Description
Patient level of consciousness
Timepoint
During endoscopy
Method of measurement
Assess the patient's level of consciousness based on the Glasgow Coma Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, 30 cc of promethazine syrup in 100 cc of drinking water made by Emad Darman Pars Pharmaceutical Company (1mg /1cc) will be given to the patient one hour before endoscopy by someone other than the endoscopist.
Category
Treatment - Drugs

2

Description
Control group: Patients will be given a solution of 50 g of glucose in 100 cc of drinking water half an hour before the upper gastrointestinal endoscopy.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mohammad Reza Pashaee
Street address
Imam Khomeini Hospital; Ershad boulevard
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5714783734
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Pashaee.m@umsu.ac.ir

2

Recruitment center
Name of recruitment center
Talegani hospital
Full name of responsible person
Mohammad Reza Pashaee
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Hospital_taleghani@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
Street address
Urmia University of Medical Sciences; Resalat boulevard
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East Azarbaijan
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5714783734
Phone
+98 44 3223 4897
Email
i.mohebbi@umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Mohammad Reza Pashaee
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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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