

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

complications, patient anxiety, patient level of consciousness

#### 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 ,

#### 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 Pashae

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3198 8001

##### Email address

pashae.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 Pashae

##### **Street address**

Imam Khomeini Hospital; Ershad boulevard

##### **City**

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### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Talegani hospital

##### **Full name of responsible person**

Mohammad Reza Pashae

##### **Street address**

Kashani st, Talegani Hospital

##### **City**

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##### **Province**

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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  
**City**  
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East Azarbaijan  
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**Phone**  
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**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 Pashae  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Internal Medicine

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## Person responsible for scientific inquiries

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**Position**  
Associate professor  
**Latest degree**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

#### Contact

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Oroumia University of Medical Sciences  
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**Position**  
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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