

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of pre-emptive metoclopramide and ondansetron on patients' pain, discomfort and nausea associated with NG Tube insertion

#### Protocol summary

##### Study aim

Determine the effect of Ondansetron injection before NG-Tube on the severity of pain, discomfort and nausea and vomiting caused by NG-Tube. Determine the effect of Metoclopramide injection before NG-Tube on the severity of pain, discomfort and nausea and vomiting caused by NG-Tube. Comparison of the effect of intravenous Metoclopramide and Ondansetron on the severity of pain, discomfort and nausea and vomiting caused by NG-Tube.

##### Design

A randomized, double-blind, placebo-controlled clinical trial

##### Settings and conduct

The study is performed in the hospital emergency department, in patients who require NG tube. Patients were randomly divided into ondansetron, metoclopramide and placebo groups. The project associate will label the syringes without the knowledge of the researcher, physician, nurse, and patient evaluator, and all NG tube insertions will be performed by a person who is unaware of the placement into groups. The degree of discomfort, the severity of pain and nausea will be assessed immediately, 30 and 60 minutes after the procedure using the VAS criteria.

##### Participants/Inclusion and exclusion criteria

Patients with an indication of NG tube and over 18 years old who are willing to participate in the study are included. Patients with unconsciousness; pregnancy; unstable hemodynamic status; nasal bleeding; nasal anatomical problems; sensitivity to metoclopramide and ondansetron; use of metoclopramide and ondansetron interfering drugs; patients presenting with nausea and vomiting; trauma patients and patients have more than twice attempted a NGT insertion. Yard is not included in the study.

##### Intervention groups

For the group1, 10 mg ondansetron and for the group2, 10 mg metoclopramide administered intravenously 15

minutes before the procedure, and for the control group, the same volume of normal saline administered.

##### Main outcome variables

Discomfort; severity of pain; nausea

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180717040509N3**

Registration date: **2020-03-27, 1399/01/08**

Registration timing: **retrospective**

Last update: **2020-03-27, 1399/01/08**

Update count: **0**

##### Registration date

2020-03-27, 1399/01/08

##### Registrant information

##### Name

Mahboubeh Eslami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3321 7982

##### Email address

m.eslami@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2018-02-19, 1396/11/30

##### Actual recruitment start date

2017-08-23, 1396/06/01

**Actual recruitment end date**

2018-02-19, 1396/11/30

**Trial completion date**

2018-03-06, 1396/12/15

**Scientific title**

Comparison of pre-emptive metoclopramide and ondansetron on patients' pain, discomfort and nausea associated with NG Tube insertion

**Public title**

Comparison of pre-emptive metoclopramide and ondansetron on patients' pain, discomfort and nausea

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with NG tube Indication

**Exclusion criteria:**

Age less than 18 years old  
Lack of consciousness  
Patients with unstable hemodynamic status (systolic blood pressure less than 90 mmHg)  
Having a nose bleed  
Anatomical problems in the nose  
Traumatic patients  
Sensitivity to Metoclopramide and Ondansetron  
Use of Metoclopramide and Ondansetron interfering drugs  
Pregnancy  
Patients with nausea and vomiting problem  
NG tube more than twice

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **46**

Actual sample size reached: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization with Independent samples. The 46 sample units were divided into two independent groups with equal volume according to the random number table. Random Unit: individual; random tool: Random Number Table.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants, physicians, nurses, and patient evaluators are not aware of the group allocation

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

**Street address**

Moallem Ave, Moallem Square, Deputy of Research and Technology of Mazandaran University of Medical Sciences

**City**

Sari

**Province**

Mazandaran

**Postal code**

4817844818

**Approval date**

2017-08-02, 1396/05/11

**Ethics committee reference number**

IR.MAZUMS.IMAMHOSPITAL.REC.1396.2910

**Health conditions studied****1****Description of health condition studied**

Pain, nausea and discomfort from nasal-gastric tube insertion

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Pain

**Timepoint**

Immediately, 30 and 60 minutes after NG tube insertion

**Method of measurement**

Visual Analgesic Score

**2****Description**

nausea

**Timepoint**

Immediately, 30 and 60 minutes after NG tube insertion

**Method of measurement**

Visual Analgesic Score

**3****Description**

discomfort

**Timepoint**

Immediately, 30 and 60 minutes after NG tube insertion  
**Method of measurement**  
Visual Analgesic Score

## Secondary outcomes

### 1

#### **Description**

Bleeding after NG tube insertion

#### **Timepoint**

Immediately, 30 and 60 minutes after NG tube placement

#### **Method of measurement**

Visual Analgesic Score

### 2

#### **Description**

Vomiting after NG tube insertion

#### **Timepoint**

Immediately, 30 and 60 minutes after NG tube placement

#### **Method of measurement**

Visual Analgesic Score

## Intervention groups

### 1

#### **Description**

Intervention group 1: for the intervention group 15 minutes before NG tube placement, 10 mg Ondansetron (manufactured by Alawi Pharmaceutical Company) injected intravenously.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 2: for the intervention group 15 minutes before NG tube placement, 10 mg Metoclopramide (manufactured by Alawi Pharmaceutical Company) injected intravenously.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Control group: patients in the control group received 10 mg of normal saline (as placebo) 15minutes before NG tube placement.

#### **Category**

Placebo

## Recruitment centers

### 1

#### **Recruitment center**

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

Emam Khomeini Hospital

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

Seyed Mohammad Hoseininejad

#### **Street address**

Razi Street

#### **City**

Sari

#### **Province**

Mazandaran

#### **Postal code**

3313148166

#### **Phone**

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#### **Email**

drhoseininejad@yahoo.com

## Sponsors / Funding sources

### 1

#### **Sponsor**

##### **Name of organization / entity**

Mazandaran University of Medical Sciences

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

Dr Majid Saeedi

##### **Street address**

Vice Chancellor for Research, Moalem Square

##### **City**

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##### **Province**

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##### **Email**

majsaeedi@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Sari 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Hoseininejad

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Medical Informatics

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Emergency Medicine

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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**

Not applicable