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

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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

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Razi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

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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

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
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Person responsible for scientific inquiries

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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