Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

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

Protocol summary

Study aim

1- Determine the effect of metoclopramide injection before NG-Tube on the severity of pain caused by NG-Tube. 2- Determine the effect of metoclopramide injections before NG-Tube injection on patient discomfort 3. Determine the effect of metoclopramide injection before NG-Tube on the incidence of NG-Tube nausea and vomiting.

Design

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

Settings and conduct

The study is performed in the hospital emergency department and in patients who require NG tube. Patients were randomly divided into case (metoclopramide) and control (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 of the patients into two groups. The degree of discomfort as well as the severity of pain and nausea will be assessed immediately and 30 and 60 minutes after the procedure using the VAS criteria in the two groups.

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 at study time, nasal anatomical problems, sensitivity to metoclopramide, use of metoclopramide 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 case group, 10 mg metoclopramide will be administered intravenously 15 minutes before the procedure, and for the control group, the same volume of normal saline will be administered.

Main outcome variables

Discomfort; severity of pain; nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180717040509N4**
Registration date: **2020-04-02, 1399/01/14**
Registration timing: **retrospective**

Last update: **2020-04-02, 1399/01/14**
Update count: **0**

Registration date

2020-04-02, 1399/01/14

Registrant information

Name

Mahboubeh Eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

2015-09-01, 1394/06/10

Actual recruitment end date

2016-02-20, 1394/12/01

Trial completion date

2016-02-20, 1394/12/01

Scientific title

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

Public title

effect of metoclopramide in pain and nausea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with NG tube Indication

Exclusion criteria:

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 Use of metoclopramide interfering drugs (anticholinergic, digoxin, levodopa, tetracycline) 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
- Data analyser

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

2015-08-31, 1394/06/09

Ethics committee reference number

IR.MAZUMS.REC.94-1477

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, nausea and discomfort

Timepoint

30 and 60 minutes after NG tube insertion

Method of measurement

Visual Analgesic Score

Secondary outcomes

1

Description

Bleeding and vomiting after NG tube insertion

Timepoint

30 and 60 minutes after NG tube placement

Method of measurement

Visual Analgesic Score

Intervention groups

1

Description

Intervention group: For the intervention group 15

minutes before NG tube placement, 10 mg metoclopramide (manufactured by Alawi Pharmaceutical Company) will be injected intravenously.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group will receive 10 mg of normal saline (as placebo) 15 minutes 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

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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

Asociate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

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