

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of Pre-emptive 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 insertion on the severity of pain, patient discomfort, nausea and vomiting caused by NG-Tube.

Design

Randomized clinical trial study (phase 3) with a sample size of 46 patients with control group, with parallel groups, double blind.

Settings and conduct

The study performed in the hospital emergency department and in patients who required NG tube. Patients were randomly divided into case (ondansetron) and control (placebo) groups. The project associate labeled the syringes without awareness of researcher, physician, nurse and patient evaluator. All NG tube insertions performed by a person who was unaware of the placement of the patients into two groups. The degree of discomfort as well as the severity of pain and nausea 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 was willing to participate in the study included. Patients with unconsciousness; pregnancy; unstable hemodynamic status; nasal bleeding; nasal anatomical problems; sensitivity to ondansetron; use ondansetron interfering drugs; patients presenting with nausea and vomiting; trauma patients and patients have more than twice attempted a NGT insertion. Yards not included in the study.

Intervention groups

For the case group, 10 mg Ondansetron 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: **IRCT20180717040509N5**

Registration date: **2020-10-29, 1399/08/08**

Registration timing: **retrospective**

Last update: **2020-10-29, 1399/08/08**

Update count: **0**

Registration date

2020-10-29, 1399/08/08

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

2018-01-05, 1396/10/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

2018-01-05, 1396/10/15

Actual recruitment end date

2018-07-06, 1397/04/15

Trial completion date

2018-07-21, 1397/04/30

Scientific title

Efficacy of Pre-emptive Ondansetron on Patients' pain, Discomfort and Nausea Associated with NG Tube Insertion

Public title

Effect of Ondansetron in Pain and Nausea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with NG tube Indication

Exclusion criteria:

less than 18 years old Unconsciousness 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 Ondansetron Use of Ondansetron 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

Sample size

Target sample size: **46**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Unit: Individual Random Tool: Random Number Table To create two independent groups with equal sample size, first number 46 sample units (patients) from 1 to 46, then using a table of random numbers, select 23 numbers from 1 to 46 randomly and without placement. Patients corresponding to the selected numbers will be given medication and the remaining 23 patients will be given placebo.

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

2017-12-23, 1396/10/02

Ethics committee reference number

IR.MAZUMS.REC.1396.10294

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

Immediately, 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

Immediately, 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 ondansetron (manufactured by Alawi Pharmaceutical Company) was injected intravenously.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group received 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

Street address

Razi Street

City

Sari

Province

Mazandaran

Postal code

۳۳۱۳۱ - ۴۸۱۶۶

Phone

+98 11 3336 1700

Fax

+98 11 3336 3754

Email

drhoseininejad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeidi

Street address

Moalem Square

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3325 7230

Fax

+98 11 3326 1244

Email

majsaeedi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Street address

Amir Mazandarani Street

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 1700

Fax

+98 11 3337 0881

Email

drhoseininejad@yahoo.com

Person responsible for scientific 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

Street address

Amir Mazandarani Street

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 1700

Fax

+98 11 3337 0881

Email

drhoseininejad@yahoo.com

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

Mazandaran University of Medical Sciences

Full name of responsible person

Mahboubeh Eslami

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Medical Informatics

Street address

Emam Khomeini Hospital, Amir Mazandarani Street

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3321 7982

Fax**Email**

m.eslami@mazums.ac.ir

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

Not applicable

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

Not applicable

Data Dictionary

Not applicable