Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Gastric residual volume evaluation with ultrasonography after intravenous ondansetron and metoclopramide and neostigmine :A Double Blind Randomized clinical Trial

Protocol summary

Study aim

Comparison of the therapeutic effect of ondansetron, metoclopramide and neostigmine in reducing gastric residual volume in intensive care unit patients under mechanical ventilation

Design

Our study is the clinical trials of Phase 3, which focus on the effects of the three drugs ondansetron and neostigmine and metoclopramide on the gastric residual volume according to the three groups of ten that patients are using from the random table to these three groups by examining the three groups of the original sample size.

Settings and conduct

Our study group selected patients with mechanical ventilation attached to the nasogastric tube who will be admitted to the medical intensive care unit of Masih Daneshvari. And will be ultrasound by an intensive care physician who is not aware of the type of drug being administered

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 to 80 years, Patients hospitalized in ICU, Patients with nasogastric tube or percutaneous gastrostomy tube Exclusion criteria: Do not place the nasal gastric tube in the stomach,Prisoners, Ileus, Long-term fasting planning,The remaining volume of the stomach is not examined by nurses for any reason.

Intervention groups

Group: Ondansetron: Patients are given 8 mg of ondansetron intravenously infused twice daily for 20 minutes. Group: Metoclopramide: Patients are given 10 mg intravenous metoclopramide infusion three times daily for 20 minutes. Group: Neostigmine: Patients given 2.5 mg intravenous neostigmine infusion within 20 minutes once daily And after five half-lives of drugs, the volume of the gastric antrum of the patients was measured by ultrasonography on four consecutive days 3 hours after gavage.

Main outcome variables

Gastric residual volume on ultrasound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190215042716N1**
Registration date: **2020-01-11, 1398/10/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-11, 1398/10/21**
Update count: **0**

Registration date

2020-01-11, 1398/10/21

Registrant information

Name

navid shafigh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8801 3378

Email address

n.shafigh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-22, 1398/05/31

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Gastric residual volume evaluation with ultrasonography after intravenous ondansetron and metoclopramide and neostigmine :A Double Blind Randomized clinical Trial

Public title

Gastric residual volume evaluation with ultrasonography after intravenous ondansetron and metoclopramide and neostigmine :A Double Blind Randomized clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18 to 80 years Patients hospitalized in ICU Patients with nasogastric tube or percutaneous gastrostomy tube

Exclusion criteria:

Do not place the nasal gastric tube in the stomach Prisoners Ileus Long-term fasting planning The remaining volume of the stomach is not examined by nurses for any reason

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who met the inclusion criteria were selected by random number table from left to right reading method. The numbers were between 00 and33 in group A (ondansetron) and patients with numbers between 33 and 66in group B (metoclopramide) and patients with numbers from 66 to99were divided into intervention group C (Neostigmine) . (Randomized Table is a set of numbers that are generated without a specific pattern and order in a completely random way and are tabulated. In order to use this table, the researcher must pre-determine the numbers to read and the default for the intervention group numbers).

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients and their legal guardians will first receive consent and patients will be included in the study, and this study will be conducted according to the ethical standards stated in the 1964 Helsinki Declaration. Then the patients and their legal counsel. It is explained that all drugs are common drugs in our treatment and our study examines their superiority over each other. The nurses will then give the patients a group of drugs that are perfectly matched in shape, color and packaging, and then sonographed by a intensive care physician who has no knowledge of the drug being administered and the remaining gastric volume measured. The information is then subdivided into three groups by the data analyzer and analyzed

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences and Health Services

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-12-01, 1398/09/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.453

Health conditions studied

1

Description of health condition studied

Gastric volume after gavage

ICD-10 code

K21.9

ICD-10 code description

Gastro-esophageal reflux disease without esophagitis

Primary outcomes

1

Description

Size of gastric residual volume on ultrasound

Timepoint

Patients were studied after 5 half-lives of drug from the third day and 4 hours after morning gavage for the next 4 days.

Method of measurement

Sonography device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Ondansetron: Patients are given 8 mg intravenous ondansetron twice daily for 20 minutes and after five half-lives of medication their gastric volume is measured with sonography four consecutive days 3 hours after gavage.

Category

Treatment - Drugs

2

Description

Intervention group 2: Metoclopramide: Patients are given 10 mg intravenous metoclopramide infused three times daily for 20 minutes and after five half-lives of medication their gastric volume is measured with sonography four consecutive days 3 hours after gavage.

Category

Treatment - Drugs

3

Description

Intervention group3: Neostigmine: Patients are given 2.5 mg intravenous infusion neostigmine for 20 minutes once daily and after five half-lives of medication their gastric volume is measured with sonography four consecutive days 3 hours after gavage.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari hospital

Full name of responsible person

Navid Shafigh

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout,

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navid_shafigh2005@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Babak Shokri

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Navid Shafigh

Position

Residency

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All potential data can be shared after unidentifiable people
When the data will become available and for how long
Start of access period from 1400
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Help to research
From where data/document is obtainable
navid_shafigh2005@yahoo.com
What processes are involved for a request to access data/document
Once the email has been sent and the email confirmation has been valid, the documentation will be sent to their email within one month.
Comments