Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparing the effect of intravenous neostigmine and metoclopramide on gastric residual volume of mechanically ventilated intensive care unit patients

Protocol summary

Study aim
Comparing the effect of intravenous neostigmine and metoclopramide on gastric residual volume of mechanically ventilated intensive care unit patients

Design
This assessment is a clinical trial in phase 3, patients with inclusion criteria for study, are considered as study group. In this study, 100 patients are selected. Patients are categorized based on non randomization method, 50 patients in the neostigmine group and 50 patients in the metoclopramide group. Accordingly, before starting the drug infusion and 3, 6, 9 and 12 hours after the start of the infusion, the gastric residual volume is evaluated by aspirate with a gavage syringe.

Settings and conduct
This study was carried out as a clinical trial at the Khatam Al Anbia Hospital in Zahedan, Also the study will also be single blinded in which patients will be blinded in study.

Participants/Inclusion and exclusion criteria
Inclusion criteria included as age between 20 and 50 years, patients under mechanical ventilation and patients with enteral nutrition through nasogastric tube. Also exclusion criteria included as previous use of beta blockers, heart block, bradycardia (heart rate less than 60) before inclusion, hypothermia in the form of central temperature below 35 degrees, kidney Failure (CR> 1.5), use erythromycin or cisapride within 8 hours before starting the study, recent surgery on stomach or digestive tract within the last ten days, signs and symptoms of bowel obstruction, pregnancy and lactation, active bronchospasm, extrapyramidal symptoms, sensitivity to neostigmine and active gastrointestinal bleeding.

Intervention groups
In the first group, neostigmine was used at 2.5 mg / 100 ml of normal saline and In the second group used metoclopramide at a dose of 10 mg / 100 ml of normal saline.

Main outcome variables
gastric residual volume

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190804044432N1**
Registration date: **2019-08-18, 1398/05/27**
Registration timing: **prospective**

Last update: **2019-08-18, 1398/05/27**
Update count: **0**

Registration date
2019-08-18, 1398/05/27

Registrant information

Name
Sara Saneie moqadam

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-08, 1398/06/17

Expected recruitment end date
2020-09-06, 1399/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of intravenous neostigmine and metoclopramide on gastric residual volume of mechanically ventilated intensive care unit patients

Public title

Comparing neostigmine and metoclopramide on gastric residual volume

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 50 years Patients under mechanical ventilation Patients with enteral nutrition through nasogastric tube

Exclusion criteria:

Previous use of beta blockers Heart Block Bradycardia (heart rate less than 60) before inclusion Hypothermia in the form of central temperature below 35 degrees Kidney Failure (CR> 1.5) Use Erythromycin or Cisapride within 8 hours before starting the study Recent surgery on stomach or digestive tract within the last ten days Signs and symptoms of bowel obstruction Pregnancy and lactation Active bronchospasm Extrapyramidal symptoms Sensitivity to Neostigmine Active gastrointestinal bleeding

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

This means that patients in groups do not know the used drugs, and drugs has similar packaging.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

9816743463, Zahedan University of Medical Sciences, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan

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Province

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Postal code

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Approval date

2019-07-27, 1398/05/05

Ethics committee reference number

IR.ZAUMS.REC.1398.185

Health conditions studied

1

Description of health condition studied

dilatation of volume

ICD-10 code

K31.0

ICD-10 code description

Acute dilatation of stomach

Primary outcomes

1

Description

gastric residual volume

Timepoint

Before starting the drug infusion and 3, 6, 9 and 12 hours after the start of the infusion

Method of measurement

Aspirate with a gavage syringe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first group, neostigmine, manufactured by Caspian Tamin Pharmaceutical Company, was used at 2.5 mg / 100 ml of normal saline, intravenously and one time.

Category

Treatment - Drugs

2

Description
Intervention group: In the second group used metoclopramide, manufactured by Caspian Tamin Pharmaceutical Company, at a dose of 10 mg / 100 ml of normal saline, intravenously and one time.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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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
Zahedan 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
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Position
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available