

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

Country

Iran (Islamic Republic of)

Phone

+98 54 3322 6841

Email address

sms18768@yahoo.com

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 Extrapyrarnidal 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

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

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

Khatam Al Anbia Hospital

Full name of responsible person

Masome Khoshfetrat

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9815733169, Jamejam Avenue, Zahedan, Sistan and Baluchestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohammad Reza Shahraki

Street address

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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

Zahedan University of Medical Sciences

Full name of responsible person

Sara Saneie Moqadam

Position

Resident of Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Province

Sistan-va-Balouchestan

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