Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Neostigmine and Metoclopramide on gastric residual volume in mechanically ventilated ICU patients

Protocol summary

Summary

The aim of this double blind randomized clinical trial is to compare the effect of Metoclopramide and Neostigmine on gastric residual volume in mechanically ventilated ICU patients. 60 patients, who are qualified for study entry, randomly allocate in two equal 30patients intervention groups. The first group receives 2.5mg Neostigmine and the second group receives 10 mg Metoclopramide in 100 cc Normal Saline which infused at 30 minutes. Then gastric residual volume will be checked 0, 3, 6, 9 and 12 hours after intervention. Also Heart rate, Blood pressure, Na, K, Mg, Hb, WBC, Albumin and SOFA are measured before intervention. After collecting and classifying of information, data will be analyzed with SPSS19.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412044365N18**
Registration date: **2014-12-17, 1393/09/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-17, 1393/09/26

Registrant information

Name

Afshin Gholipour Baradari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2013-02-01, 1391/11/13

Expected recruitment end date

2014-02-01, 1392/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Neostigmine and Metoclopramide on gastric residual volume in mechanically ventilated ICU patients

Public title

Comparison of the effect of Neostigmine and Metoclopramide on gastric residual volume in mechanically ventilated ICU patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient family agreement and informed written consent; under mechanical ventilation; nutrition via gastric tube; gastric residual volume greater than 120 cc; age between 20 and 70 years Exclusion criteria: diabetes; heart rate<60; heart blocks and arrhythmias; systolic BP less 90 mmHg; hypothermia (core temperature less 35); renal failure (Serum Creatinin more 1.5 in two consecutive test); prokinetic agents consumption during 8 hours before intervention; recent surgery on GI tract within 10 days; pregnancy and breast feeding; extrapyramidal sign; bronchospasm; hypokalemia (K less 3 meq/L); known sensitivity to

Neostigmine and metoclopramide; GI bleeding

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethic committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Postal code

46175866

Approval date

2013-01-30, 1391/11/11

Ethics committee reference number

91-204

Health conditions studied

1

Description of health condition studied

gastric residual volume

ICD-10 code

K31.0

ICD-10 code description

acute dilatation of stomach

Primary outcomes

1

Description

gastric residual volume

Timepoint

0,3,6,9,12 hours after intervention

Method of measurement

Gastric lavage

Secondary outcomes

1

Description

Albumin, Hemoglobin, WBC, Na, K, Mg

Timepoint

before trial

Method of measurement

laboratory kit

2

Description

hear rate, blood pressure

Timepoint

during trial

Method of measurement

cardiac monitoring

3

Description

SOFA

Timepoint

before trial

Method of measurement

SOFA calculator

Intervention groups

1

Description

Intrvention group 1: Neostigmine 2.5 mg in 100 ml normal saline infused during 30 minute at the beginning of trial.

Category

Treatment - Drugs

2

Description

Intrvention group 2: Metoclopramide 10 mg in 100 ml normal saline infused during 30 minute at the beginning of trial.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini General Hospital

Full name of responsible person
Afshin Gholipour Baradari, MD, CCMF, Associate Professor

Street address
Imam Khomeini general Hospital, Amir St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person
Ahmad Ali Enayati, MD

Street address
Mazandaran University of Medical Sciences, Moallem Square- Sari- Iran

City
Sari

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research of Mazandaran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Afshin Gholipour Baradari, MD

Position
CCMF, Associate Professor, Chief of ICU

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty