Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 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
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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
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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
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CCMF, Associate Professor, Chief of ICU
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Person responsible for updating data

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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