Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The effect of combination of Neostigmine and Metoclopramide on gastric residual volume in mechanically ventilated ICU patients

Protocol summary

Summary

The aim of this Triple blind randomized clinical trial is comparing the effect of Metoclopramide , Neostigmine and combination of Metoclopramide and Neostigmine on gastric residual volume in mechanically ventilated ICU patients. 90 patients, who qualified for study entry, randomly allocate in three equal 30patients intervention groups. The first group receives 2.5mg Neostigmine, the second group receives 10 mg Metoclopramide and the third group receives both of them in 100 cc Normal Saline 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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408104365N16**
Registration date: **2015-01-01, 1393/10/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-01, 1393/10/11

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

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2014-03-01, 1392/12/10

Expected recruitment end date

2015-02-01, 1393/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combination of Neostigmine and Metoclopramide on gastric residual volume in mechanically ventilated ICU patients

Public title

Combination of Neostigmine and Metoclopramide to reduce 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 60 years Exclusion criteria: diabetes; heart rate<60; heart blocks and arrhythmias; systolic BP<90 mmHg; hypothermia (core temperature<35); renal failure (serum Creatinin>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<3 meq/L); known sensitivity to Neostigmine and metoclopramide; GI bleeding.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mazandaran University of Medical Sciences

Street address
Mazandaran University of Medical Sciences, Moallem Square

City
sari

Postal code
46175866

Approval date
2013-12-04, 1392/09/13

Ethics committee reference number
92-163

Health conditions studied

1

Description of health condition studied
The relation of combination of Neostigmine and Metoclopramide with gastric residual volume in mechanically ventilated ICU patients

ICD-10 code

ICD-10 code description

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

3

Description
Intrvention group 3: Neostigmine 2.5 mg + 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
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Mazandaran University of Medical Sciences, Moallem Square- Sari- Iran
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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
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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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