Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of Effectiveness of Different Dosage of Neostigmine in Combination with Metoclopramide, on Gastric Residual Volume, in Enteral Nutrition, in Hospitalized Patients in Intensive Care Unit

Protocol summary

Study aim

The aim of this study was to evaluate the effect of different doses of Neostigmine in combination with Metoclopramide , on the gastric residual volume of trauma patients in the intensive care unit will be done that under enteral nutrition via NG.Tube or OG.Tube.

Design

This study is 165 patients (in three groups of 55) traumatized patients referring to Rasoul-E Akram Hospital in Tehran divided into three groups A, B and C using block randomized method

Settings and conduct

Patients who are traumatized and referring to Rasoul-E Akram hospital in Tehran and admitted to the intensive care unit. The design of the study is a double-blind, randomized controlled trial. Patients and physicians who examine the status of the patients will be blinded to the intervention type.

Participants/Inclusion and exclusion criteria

Enteral nutrition feeding; after three hours from the last gavage gastric residual volume ≥50% and age 18-60 are inclusion criteria and exclusion criteria are diabetes mellitus disease; heart rate <60 and systolic blood pressure <90.

Intervention groups

(Gold standard group): Metoclopramide will be prescribed five milligrams in every eight hours by IV.slow method during one minute. In addition, one milligram of NASTIGMINE dose in dilute solution of 100 cc Normal Saline and infusion takes in time 60 minutes. The gavage will be done three hours after the completion of the Neostigmine infusion. patients will be get 300 cc Gavage every three hours. (Intervention group 1): Metoclopramide will be prescribed five milligrams in every eight hours by IV.slow method during one minute. In addition, one and a half milligrams of NASTIGMINE dose in dilute solution of 100 cc Normal Saline and infusion takes in time 60 minutes. The gavage will be done three hours after the completion of the Neostigmine infusion. patients will be get 300 cc Gavage every three hours. (Intervention group 2): Metoclopramide will be prescribed five milligrams in every eight hours by IV.slow method during one minute. In addition, two milligrams of NASTIGMINE dose in dilute solution of 100 cc Normal Saline and infusion takes in time 60 minutes. The gavage will be done three hours after the completion of the Neostigmine infusion. patients will be get 300 cc Gavage every three hours

Main outcome variables

The gastric remaining volume after three hours is the primary outcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170903036041N1**
Registration date: **2017-12-16, 1396/09/25**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-16, 1396/09/25**
Update count: **0**

Registration date

2017-12-16, 1396/09/25

Registrant information

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Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status
Recruitment complete
Funding source
Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date
2017-06-22, 1396/04/01
Expected recruitment end date
2018-04-16, 1397/01/27
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Effectiveness of Different Dosage of Neostigmine in Combination with Metoclopramide, on Gastric Residual Volume, in Enteral Nutrition, in Hospitalized Patients in Intensive Care Unit

Public title
Evaluation of Effectiveness of Different Dosage of Neostigmine in Combination with Metoclopramide, on Gastric Residual Volume
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Enteral nutrition feeding After three hours from the last gavage gastric residual volume ≥50% Age 18-60
Exclusion criteria:
Diabetes mellitus disease Atrioventricular block Heart rate <60 Systolic blood pressure <90 Within 10 days Gastrointestinal surgery Clinical signs of Gastrointestinal obstruction Bronchospasm or Asthma history In 24 hours administration of Prokinetic drugs Sensitivity to Metoclopramide or Neostigmine Kidney failure or Creatinine >2 milligram/deciliter Hypokalemia Concomitant medication with Cyclosporine Digoxin and Monoamine Oxidase inhibitors
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **165**
Randomization (investigator's opinion)
Randomized
Randomization description
Traumatized patients divided into three groups A, B and C using block randomized method. In this study a person who is not in the study process after the admission of the patient, allocated the relevant intervention to each patient with the relevant block and notifies the director of the research team.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double blind study that patients or their companions after verifying the informed consent of the study, will be blind the type of intervention. Physicians and carers of patients which examines the clinical status of patients will be blind to the type of intervention that patients are taking.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Science
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
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Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2017-10-03, 1396/07/11
Ethics committee reference number
IR.IUMS.REC 1396.31529

Health conditions studied

1

Description of health condition studied
Gastric residual volume
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Gastric residual volume
Timepoint
three hours after the completion of the infusion
Method of measurement
Cc

Secondary outcomes

1

Description
Age
Timepoint
At the time of entering the study
Method of measurement
Chronological age

2

Description
Blood pressure
Timepoint
Recorded during the measurement of the gastric remaining volume
Method of measurement
mmHg (millimeters of mercury)

3

Description
Respiratory rate
Timepoint
Recorded during the measurement of the gastric remaining volume
Method of measurement
The number of movements indicative of inspiration and expiration per unit time

4

Description
Heart rate
Timepoint
Recorded during the measurement of the Gastric remaining volume
Method of measurement
Number of contractions of the heart per minute (bpm)

Intervention groups

1

Description
(Gold standard group): Metoclopramide will be prescribed five milligrams in every eight hours by IV.slow method during one minute. In addition, one milligram of Neostigminedose in dilute solution of 100 cc Normal Saline and infusion takes in time 60 minut
Category
Treatment - Drugs

2

Description
(Intervention group 2): Metoclopramide will be prescribed five milligrams in every eight hours by IV.slow method during one minute. In addition, two milligrams of Neostigmine dose in dilute solution of 100 cc Normal Saline and infusion takes in time 60 mi
Category
Treatment - Drugs

3

Description
(Intervention group 1): Metoclopramide will be prescribed five milligrams in every eight hours by IV.slow method during one minute. In addition, one and a half milligrams of Neostigmine dose in dilute solution of 100 cc Normal Saline and infusion takes in
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat-e Rasoul Akram hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellery for research Iran University of Medical Sciences
Full name of responsible person
Kazem Malakouti
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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 chancellery for research Iran 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
Iran University of Medical Science

Full name of responsible person
Omid Moradi Moghadam

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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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