

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 $\geq 50\%$ 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

Name

Omid Moradi Moghadam

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6653 9233

Email address

moradimoghadam.o@iums.ac.ir

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 $\geq 50\%$ 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

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

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 Neostigmine dose 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

Omid Moradi Moghadam

Street address

Hazrat-e Rasoul Akram hospital, Niyayesh St, Sattar Khan St

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 6653 9255

Fax

+98 21 6653 9255

Email

moradimoghadam.o@iums.ac.ir

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

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 6653 9255

Email

moradimoghadam.o@iums.ac.ir

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
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 912 124 4560
Fax
Email
moradimoghadam.o@iums.ac.ir
Web page address

Person responsible for scientific 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
Street address

Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 6653 9255
Fax
Email
moradimoghadam.o@iums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Omid Mordi Moghadam
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 6653 9255
Fax
Email
moradimoghadam.o@iums.ac.ir
Web page address

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