Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing efficacy and safety of metoclopramide as continuous intravenous infusion and intravenous bolus injection on enteral nutrition tolerance in critically ill patients

Protocol summary

Summary

The goals of this single center, open labeled, randomized, clinical trial are comparing efficacy and safety of metoclopramide as continuous intravenous infusion and intravenous bolus injection on enteral feeding tolerance in critically ill patients. Critically ill adult patients who are candidate to receive metoclopramide as prokinetic agent due to enteral feeding intolerance for at least 7 days during their ICU stay will be included. Patients with history of metoclopramide allergy, intolerance or any contraindication will be excluded. In this study, 40 eligible patients admitted in the general ICU of Imam Khomeini Hospital, will be assigned to receive metoclopramide 10 mg every 6 hours as slow intravenous injection within 3 minutes (group A) or metoclopramide 40mg/24-hour as continuous intravenous infusion (Group B) for 7 days. During the study period, patients will be monitored as daily interval for enteral feeding intolerance including clinical signs and symptoms of gastrointestinal intolerance (nausea, vomiting, diarrhea and regurgitation) and gastric residual volume. Hemodynamic, cardiovascular and neurological monitoring will be considered for all patients during the study period. Also patients will be followed for any adverse reaction related to metoclopramide. At the end of the study, efficacy and safety of two methods of metoclopramide administration will be compared in the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601213449N20**
Registration date: **2016-02-08, 1394/11/19**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-02-08, 1394/11/19

Registrant information

Name
Hossein Khalili
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6695 4715
Email address
khalilih@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2015-09-21, 1394/06/30

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy and safety of metoclopramide as continuous intravenous infusion and intravenous bolus injection on enteral nutrition tolerance in critically ill patients

Public title
Metoclopramide and enteral nutrition
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Critically ill adult patients who are candidate to receive metoclopramide as prokinetic agent due to enteral feeding intolerance (defined as gastric residual volume equal to or greater than 250 ml concomitant with symptoms of nausea, vomiting, and regurgitation or gastric residual volume more than 500 ml during 24 hours of enteral feeding) will be included. Exclusion criteria: Patients with metoclopramide allergy; metoclopramide intolerance; uncontrolled ventricular arrhythmia; extrapyramidal reactions; seizure; head trauma; signs and symptoms of increased intracranial pressure
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Tehran University of Medical Sciences
Street address
4th floor, No. 23, Poursina Street, Keshavarz Blvd., Tehran University of Medical Sciences
City
Tehran
Postal code
Approval date
2015-09-16, 1394/06/25
Ethics committee reference number
IR.TUMS.1394.784

Health conditions studied

1

Description of health condition studied
Gastroparesis
ICD-10 code
K90.4
ICD-10 code description
Malabsorption due to intolerance, not elsewhere classified

Primary outcomes

1

Description
Enteral feeding intolerance
Timepoint
Daily
Method of measurement
Gastric residual will be measured between the enteral feeding intervals. Intolerance defined as gastric residual volume more than 250 ml with clinical symptoms or gastric residual volume more than 500 ml by itself.

Secondary outcomes

1

Description
Metoclopramide side effects
Timepoint
Daily
Method of measurement
Patients will be monitored regarding metoclopramide related adverse reactions including cardiovascular (blood pressure and cardiac rhythm), neurological (extrapyramidal signs and seizure) and gastrointestinal (diarrhea).

Intervention groups

1

Description
Intervention group: Metoclopramide infusion with rate of 40mg/24-hour for 7 days
Category
Treatment - Drugs

2

Description
Control group: Metoclopramide intravenous injection with dose of 10 mg every 6 hours for 7 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Hossein Khalili
Street address
General ICU, Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Masoud Yunesian
Street address
Ghods Ave.
City
Tehran
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, Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Hossein Khalili
Position
Pharm. D
Other areas of specialty/work
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences
City
Tehran
Postal code
Phone
+98 21 6119 2112
Fax
Email
khalilih@tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hossein Khalili
Position
Pharm. D
Other areas of specialty/work
Street address
Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences
City
Tehran
Postal code
Phone
+98 21 6119 2112
Fax
Email
khalilih@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masoume Malekolkottab
Position
Pharrm. D
Other areas of specialty/work
Street address
City
Tehran
Postal code
Phone
+98 21 6619 2112
Fax
Email
m_malekokottab@yahoo.com
Web page address

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