

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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

Pharm. 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