Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Comparing efficacy and safety of enteral nutrition with and without ranitidine in prevention of gastric ulcer in critically ill patients

Protocol summary

Summary

The goals of this single center, open labeled, randomized, clinical trial are comparing efficacy and safety of enteral nutrition with and without ranitidine on prevention of gastric ulcer in critically ill patients. Critically ill patients with indication of gastric ulcer prophylaxis and without contraindication for enteral feeding who are hospitalized for at least for 7 days in ICU will be included. Patients with active gastric ulcer or bleeding, enteral nutrition intolerance, coagulopathy and head trauma will be excluded. 50 patients with inclusions will be recruited based on the simple randomization method in groups A or B. Ranitidine (50 mg every 8 hours as slow intravenous injection) plus enteral nutrition for 7 days will be considered for patients in group A. Patients in group B will be receive only enteral nutrition during the study period. During the stduy patients will be monitored for gastrointestinal complications including enteral feeding intolerance, coffe ground secretions fron tube feeding, melena and hematemesis. Also patients will be assessed for episodes of aspiration pneumonia and airhead. Finally efficacy and safety of enteral nutrition with and without ranitidine will be compared in critically ill patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604213449N21**
Registration date: **2016-05-30, 1395/03/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-30, 1395/03/10

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy and safety of enteral nutrition with and without ranitidine in prevention of gastric ulcer in critically ill patients

Public title

Enteral nutrition and gastric ulcer in critically ill patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Critically ill adult patients with indication of gastric ulcer prophylaxis without contraindication for enteral nutrition will be recruited.

Exclusion criteria: Patients with history of active gastric ulcer in month before inclusion; gastric bleeding in time of hospitalization; coagulopathy; enteral feeding intolerance; severe burn; head trauma; increased intracranial pressure

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

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
2016-05-14, 1395/02/25

Ethics committee reference number
IR.TUMS.REC.1395.2592

Health conditions studied

1

Description of health condition studied
Gastric Ulcer

ICD-10 code
K25

ICD-10 code description
Stress Induced Gastric Ulcer

Primary outcomes

1

Description
Stress induced gastric ulcer

Timepoint
At baseline and daily for 7 days

Method of measurement
Evaluation of gastrointestinal symptoms including gastric intolerance, coffe ground secretions from tube feeding, melena and hematemesis

Secondary outcomes

1

Description
Complications of gastric acid suppressant agents

Timepoint
At baseline and daily for 7 days

Method of measurement
Evaluation of patients for pneumonia and diarrehea

Intervention groups

1

Description
Intervention group: Enteral feeding as 50 ml at beginning and then increasing 50 ml every 3 hours up to 200 ml every 3 hours.

Category
Prevention

2

Description
Control group: Enteral feeding (same as the intervention group) plus ranitidine amp, 50 mg every 8 hours as slow intravenous injection for 7 days.

Category
Prevention

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

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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