

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 from 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

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4715

Email address

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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, coffee 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 diarrhea

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

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

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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