Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effect of prepared powder for Omeprazole suspension on gastric pH of ICU patients

Protocol summary

Summary

Stress related mucosal disease is common in intensive care unit. The prevention of gastrointestinal bleeding with the use of gastric acid-lowering agents leads to a reduction in major bleeding in patients.This study is designed to evaluate the effect of Laboratory prepared powder for suspension of Omeprazole on the gastric pH in critically ill patients. Thirty patients above sixteen years old with nasogastric tube in place and at least one additional risk factor for upper gastrointestinal bleeding were included in the study. The patients with active gastrointestinal bleeding, high dose of corticosteroids and Hypersensitivity to omeprazole were excluded from this study.The patients were treated with prophylaxis of suspension of omeprazole for at least fourteen days. Gastric aspirates were sampled via gavage syringe before and 2 hours after the administration of the drug. The patients gastric pH was measured and evaluated via pH-meter.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062120592N6**
Registration date: **2016-08-09, 1395/05/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-09, 1395/05/19

Registrant information

Name

Seyed Mohammad Reza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences، Faculty of Pharmacy

Expected recruitment start date

2015-07-01, 1394/04/10

Expected recruitment end date

2016-05-30, 1395/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of prepared powder for Omeprazole suspension on gastric pH of ICU patients

Public title

The effect of Omeprazole suspension on gastric pH of ICU patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age of ≥16 yrs of age; anticipated stay of ≥72 hrs in ICU; required mechanical ventilation more than 48 hrs; APACHE II score ≥11; have a nasogastric or orogastric tube in place; have at least one additional risk factor for upper GI bleeding Exclusion criteria: status of no CPR; delay of >48 hrs from time of initial eligibility; history of gastric surgery; allergy to omeprazole; active GI bleeding; significant risk of swallowing blood; admission for upper GI surgery; known upper GI Lesions

that might bleed; inability to take a suspension by nasogastric tube;end-stage liver disease

Age
From **16 years** old to **95 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

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
Shahid Beheshti University of Medical science,faculty of Pharmacy

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Valiasr Niayesh crossing,shahid beheshti university

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14155-6153

Approval date
2014-01-26, 1392/11/06

Ethics committee reference number
SBMU.REC.1392.614

Health conditions studied

1

Description of health condition studied
erosion (acute) of stomach

ICD-10 code
k25

ICD-10 code description
Gastric ulcer

Primary outcomes

1

Description
mean gastric pH

Timepoint
before and 1-2.5 hrs after drug administration

Method of measurement
pH meter

Secondary outcomes

1

Description
active upper GI bleeding

Timepoint
every day up to 14 days

Method of measurement
Gastroccult test

Intervention groups

1

Description
patients for prophylaxis treated with omeprazol suspension (40mg)every day via nasogastric tube for 14 days. Gastric aspirates were sampled before(empty stomach) and 1.5-2 hours after administration of the drug.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Masih Daneshvari National Research Institute of Tuberculosis and Lung Disease

Full name of responsible person
Doctor seyed mohammadreza Hashemian

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Masih Daneshvari hospital, Poorebtehaj St., Darabad, Niavaran Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Fanak Fahimi

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No. 2660, Vali-e-Asr Ave., Tehran 1991953381, Iran

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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