Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison of nasogastric pantoprazole suspension and intravenouse pantoprazole in prevention of peptic ulcer for critically ill patients with mechanical ventilation support: effects on 24-h intragastric pH.

Protocol summary

Summary

The purpose of this randomized clinical trial is to compare the efficacy of pantoprazole for prevention of peptic ulcer when administered as a suspension in sodium bicarbonate solution versus the IV injection. 66 patients with age more than 18 years and with support of mechanical ventilation at least for 48 hours and nasogastric tube at medical and surgical ICUs of Rasoul - e-Akram Hospital are enrolled.Intragastric pH is monitored at baseline and on days 1 and 3 after beginning the treatment in all patients.33 patients (group A)receive :pantoprazole 40 mg once daily intravenously and 33 patients(group B) receive: 25 cc of 2mg/ml simplified formulated pantoprazole suspension (50 mg pantoprazole) once daily nasogastrically and according to 75% bioavailability for suspension at last this dose equal to 40mg oral pantoprazole .All patients will receive their treatment regimen for at least 24 hours and up to 14 days depending on their survival, length of stay and removal of nasogastric tube.And if possible, the follow up will be done for28 days. For both groups of patients, blood samples are collected before the drug administration and in different times upto 24 hours afterward for measurement of pantoprazole concentration by high-performance liquid chromatography and estimation of pharmacokinetic values .The intragastric pH results and pharmacokinetic values,any episode of gastrointestinal bleeding after starting treatment and any probable drug side effects are recorded and statistical analysis is performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070220178N5**
Registration date: **2015-08-12, 1394/05/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-12, 1394/05/21

Registrant information

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences,Rasoul Akram Hospital,Colorectal Research Center

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of nasogastric pantoprazole suspension

and intravenouse pantoprazole in prevention of peptic ulcer for critically ill patients with mechanical ventilation support: effects on 24-h intragastric pH.

Public title
Efficacy of pantoprazole suspension for prevention of peptic ulcer.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:Patients older than 18 years who are admitted to medical and surgical ICUs with support of mechanical ventilation at least for 48 hours and nasogastric tube . Exclusion criteria:active gastrointestinal bleeding,allergic history to pantoprazole ,co-administeration of prokinetic and other acid reducing drugs,past history of gastric surgery,nasogastric tube intolerance,liver failure,pregnancy, lactation,unexpected intragastric pH<0.8 and/or >10.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **66**
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
Iran University of Medical Sciences Ethics Committee
Street address
Iran University of Medical Sciences,West Shahid Hemmat Highway,Intersection of Chamran and Sheikh Fazlollah Noori,
City
Tehran
Postal code
Approval date
2015-06-30, 1394/04/09
Ethics committee reference number
IR.IUMS.REC.1394.26271

Health conditions studied

1

Description of health condition studied
peptic ulcer prevention
ICD-10 code
k27
ICD-10 code description
Peptic ulcer, site unspecified

Primary outcomes

1

Description
peptic ulcer prevention
Timepoint
basic ,first day,third day
Method of measurement
24 hours intragastric PH monitoring

Secondary outcomes

1

Description
gastrointestinal bleeding rate after treatment intervention
Timepoint
1,3 ,7,14 and 28 days after treatment intervention
Method of measurement
Data gathering sheet and nasogastric tube exam

2

Description
Drug adverse effect such as pneumonia rate
Timepoint
3 ,7, 14 and 28 days after treatment intervention
Method of measurement
Sign and symptom gathering sheet and chest x-ray

3

Description
frequency ofunderlying etiologic factore for mechanical ventilation support
Timepoint
at the begining of treatment
Method of measurement
Data gathering sheet

Intervention groups

1

Description
group A:pantoprazole, 40 mg intravenous once daily.The

IV solution will be prepared by injecting 10 ml of 0.9% sodium chloride injection into the vial containing the lyophilized powder.This solution will be then further dilluted with 90 ml of sodium chloride injection,The reconstituted solution will be infused over a period of 15 minutes.

Category

Prevention

2

Description

group B: 25 cc of 2mg/ml simplified formulated pantoprazole suspension (50 mg pantoprazole) once daily nasogastrically and according to 75% bioavailability for suspension at last this dose equal to pantoprazole tablet 40mg.The pantoprazole suspension is prepared four hours before administration. Two 40-mg pantoprazole tablet is ground into a fine powder . The powder is transferred to a glass container, and rinsed twice with 10 mL of 4.2% (0.5 M) sodium bicarbonate solution. The container is closed and shaked for 10 minutes until a uniform suspension formed. The suspension is transferred to a 40-mL polypropylene syringe. The glass container is rinsed twice with 10 mL of 4.2% sodium bicarbonate solution again, and the suspension is added to the syringe. The total volume of the suspension is 40 mL, and the pantoprazole concentration is 2 mg/mL. The suspension is protected from light.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Colorectal Research Center, Rasoul Akram Hospital

Full name of responsible person

Marjan Mokhtare

Street address

Sattarkhan Street, Niayesh Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences,Rasoul Akram Hospital,Colorectal Research Center

Full name of responsible person

Shahram Agah

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences,Rasoul Akram Hospital,Colorectal Research Center

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

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Full name of responsible person

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Gastroenterologist and Hepatologist, Assistant professor

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