

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

A comparison of nasogastric pantoprazole suspension and intravenous 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. Intra-gastric 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 for 28 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 intra-gastric 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

Name

Marjan Mokhtare

Name of organization / entity

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

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 2845

Email address

mokhtare.m@iums.ac.ir

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

IR.IUMS.REC.1394.26271

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-administration 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

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 of underlying etiologic factors for mechanical ventilation support

Timepoint

at the beginning 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 diluted 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 shaken 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

Street address

Sattarkhan Street, Niayesh Street

City

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**

Colorectal Research Center, Rasoul Akram Hospital

Full name of responsible person

Marjan Mokhtare

Position

Gastroenterologist and Hepatologist, Assistant professor

Other areas of specialty/work**Street address**

Sattarkhan Street, Niayesh Street

City

Tehran

Postal code**Phone**

+98 21 6655 4790

Fax**Email**

mokhtare.m@iums.ac.ir-
marjanmokhtare@yahoo.com-
mokhtaredr@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Colorectal Research Center, Rasoul Akram Hospital

Full name of responsible person

Marjan Mokhtare

Position

Gastroenterologist and Hepatologist, Assistant professor

Other areas of specialty/work**Street address**

Colorectal Research Center, Rasoul Akram Hospital, Niayesh Street, Sattarkhan Street

City

Tehran

Postal code

Phone

+98 21 6655 4790

Fax**Email**

mokhtare.m@iums.ac.ir-
marjanmokhtare@yahoo.com-
mokhtaredr@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Rasoul Akram Hospital, Colorectal Research Center

Full name of responsible person

Somayeh Nasiripour

Position

Pharmacotherapy Speciality/Assistant professor

Other areas of specialty/work**Street address**

Satarkhan Avenue, Niayesh street

City

Tehran

Postal code**Phone**

+98 21 6655 4790

Fax**Email**

babak.somi@gmail.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