

# 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**

Registration timing: **registered\_while\_recruiting**

#### **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.

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**

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##### **Email address**

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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

#### **General information**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT2015070220178N5**

Registration date: **2015-08-12, 1394/05/21**

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

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**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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**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**

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Gastroenterologist and Hepatologist, Assistant professor

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**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*