

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

comparison of the effectiveness of parenteral Pantoprazole with oral Pantoprazole plus bicarbonate on gastric pH in children

Protocol summary

Study aim

Evaluating the effect of oral Pantoprazole in stomach pH

Design

open-label phase 3 controlled paralleled clinical trial of 80 patients by simple randomization

Settings and conduct

Eighty patients aged 0-15 years will be recruited in the study regarding inclusion and exclusion criteria. The patients will be admitted to Mofid children hospital and will be randomly divided into two intervention and control groups; in the intervention group, oral pantoprazole dissolved in Bicarbonate 8.4 percent solution by 1 milligram per kilogram dose every 12 hours. In the control group, patients receive standard treatment of parenteral Pantoprazole by 1 milligram per kilogram dose every 12 hours. After 48 hours gastric pH would be measured by nasogastric tube sample. Patient will follow-up for 2 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pediatric intensive care unit admission, Mechanical ventilation, Naso-gastric tube placement.
Exclusion criteria: Pantoprazole sensitivity, Active gastrointestinal bleeding, History of gastrointestinal ulcer.

Intervention groups

Eighty patients aged 0-15 years will be recruited in the study regarding inclusion and exclusion criteria. The patients will be admitted to Mofid children hospital and will be randomly divided into two intervention and control groups; in the intervention group, oral pantoprazole dissolved in Bicarbonate 8.4 percent solution by 1 milligram per kilogram dose every 12 hours. In the control group, patients receive standard treatment of parenteral Pantoprazole by 1 milligram per kilogram dose every 12 hours.

Main outcome variables

Stress ulcer occurrence; Diarrhea occurrence; Pneumonia occurrence; Morbidity and mortality

General information

Reason for update

There was a mistake in registering the actual start time of recruitment.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009475N7**

Registration date: **2020-01-21, 1398/11/01**

Registration timing: **retrospective**

Last update: **2020-04-26, 1399/02/07**

Update count: **1**

Registration date

2020-01-21, 1398/11/01

Registrant information

Name

Bahador Mirrahimi

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
Faculty of Pharmacy

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0118

Email address

mirrahimi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2019-06-22, 1398/04/01

Actual recruitment end date

2019-11-22, 1398/09/01

Trial completion date

2019-11-22, 1398/09/01

Scientific title

comparison of the effectiveness of parenteral Pantoprazole with oral Pantoprazole plus bicarbonate on gastric pH in children

Public title

comparison of the parenteral and oral Pantoprazole in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pediatric intensive care unit admission Mechanical ventilation Naso-gastric tube placement

Exclusion criteria:

Pantoprazole sensitivity Active gastrointestinal bleeding History of gastrointestinal ulcer

Age

From **1 month** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization executed by random numbers table generated by excel program. Patients individually will be allocated to intervention and control groups by odd and even succession of numbers in the table. There is no allocation concealment.

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**

کمیته اخلاق دانشگاه علوم پزشکی شهید بهشتی

Street address

Sharyati Ave., Mofid hospital

City

Tehran

Province

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Postal code

1546815514

Approval date

2019-06-10, 1398/03/20

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.080

Health conditions studied**1****Description of health condition studied**

Stress ulceration prevention

ICD-10 code

K92.81

ICD-10 code description

Gastrointestinal mucositis (ulcerative)

Primary outcomes**1****Description**

Patient's stomach pH

Timepoint

48 hours after starting treatment

Method of measurement

By litmus paper

Secondary outcomes**1****Description**

Diarrhea occurrence

Timepoint

During 14 day after treatment

Method of measurement

Nurse report

2**Description**

Pneumonia occurrence

Timepoint

During 14 day after treatment

Method of measurement

Based on diagnosis criteria

3**Description**

Morbidity and mortality

Timepoint

Until patient discharge

Method of measurement

By report

4

Description

stress ulcer occurrence

Timepoint

During 14 day after treatment

Method of measurement

gastric lavage

Intervention groups

1

Description

Intervention group: In this group patients receive oral pantoprazole dissolved in Bicarbonate 8.4 percent solution by 1 milligram per kilogram dose every 12 hours.

Category

Treatment - Drugs

2

Description

Control group: In this group patients receive standard treatment of parenteral Pantoprazole by 1 milligram per kilogram dose every 12 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid children's Hospital

Full name of responsible person

Bahador Mirrahimi

Street address

Mofid Children's Hospital, Mirdamad Junction, Shariaty Ave.

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mirrahimi@sbmu.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaee

Street address

3rd Floor, Faculty of medicine, Arabi Ave, Daneshjoo Blvd, Velenjak.

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1991953381

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mpd@sbmu.ac.ir

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Bahador Mirrahimi

Position

Asistant Profesor, Pharmacotherapy.

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The main outcome will be available.

When the data will become available and for how long

Six months after publishing data.

To whom data/document is available

The data will be available per request for people working in academic institutions.

Under which criteria data/document could be used

The data will available for using in systematic review and meta-analysis.

From where data/document is obtainable

The data will be available by contacting email; mirrahimi@sbmu.ac.ir.

What processes are involved for a request to access data/document

The data will available for using in systematic review and meta-analysis.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Bahador Mirrahimi

Position

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Latest degree

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Other areas of specialty/work

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