Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 21 8820 0118

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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
Tehran
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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+98 21 2243 9951
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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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Shahid Beheshti University of Medical Sciences

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Position
Asistant Profesor, Pharmacotherapy.

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Person responsible for updating data

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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