Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A clinical trial to compare the effects of ranitidine, pantoprazole, and sucralfate on the prevention of gastrointestinal bleeding and ventilator-associated pneumonia in children under mechanical ventilation.

Protocol summary

Study aim

To compare the effects of ranitidine, pantoprazole, and sucralfate on the prevention of gastrointestinal bleeding and ventilator-associated pneumonia in children under mechanical ventilation.

Design

In this double-blinded clinical trial with a control group, 87 children under mechanical ventilation for more than 48 hours will be selected as parallel groups using a table of random numbers.

Settings and conduct

The children under mechanical ventilation for more than 48 hours at the pediatric intensive care unit in Doctor Sheikh and Akbar Children's hospitals are selected in this study. In this double-blind study, the clinical care and those who are responsible for data collection are blind to the patients groups and the type of drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patients admitted to the pediatric care unit who have been under ventilation for at least 48 hours. Exclusion criteria: Hospital stay or mechanical ventilation less than 48 hours, gastrointestinal bleeding before the onset of the treatment, ventilator-associated pneumonia before the onset of the treatment.

Intervention groups

The first intervention group will receive 4 mg/kg/day of intravenous ranitidine 3 times per day. The second group will receive 1 mg/kg/day of intravenous pantoprazole 2 times per day. Moreover, the third group will receive 60 mg/kg/day of oral sucralfate 4 times per day.

Main outcome variables

The three intervention groups will be evaluated and compared regarding the rate of ventilator-associated pneumonia, gastrointestinal bleeding, upper airway colonization, hospital stay in the intensive care unit, and mortality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190522043672N1**
Registration date: **2020-01-18, 1398/10/28**
Registration timing: **prospective**

Last update: **2020-01-18, 1398/10/28**
Update count: **0**

Registration date

2020-01-18, 1398/10/28

Registrant information

Name

Majid Sezavar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3870 9225

Email address

sezavardm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A clinical trial to compare the effects of ranitidine, pantoprazole, and sucralfate on the prevention of gastrointestinal bleeding and ventilator-associated pneumonia in children under mechanical ventilation.

Public title
Prevention of gastrointestinal bleeding and ventilator-associated pneumonia in children under mechanical ventilation.

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
The patients admitted to the pediatric care unit who have been under ventilation for at least 48 hours.

Exclusion criteria:
Hospital stay or mechanical ventilation less than 48 hours Gastrointestinal bleeding before the onset of the treatment, Ventilator-associated pneumonia before the onset of the treatment

Age
From **1 month** old to **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **87**

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects will be randomly assigned into three groups of 29 patients with blocks of 2, 4 and 6 using randomization method. A noninvolved researcher will determine the random assignment sequencing in sample selection based on a statistical analysis system (SAS), computer software. Sequentially numbered sealed opaque envelopes will be used to conceal the sequencing. Accordingly, the participants were given codes and assigned into the intervention and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The children under mechanical ventilation for more than 48 hours at the pediatric intensive care unit in Doctor Sheikh and Akbar Children's hospitals are selected in this study. In this double-blind study, sequentially numbered sealed opaque envelopes will be used to conceal the sequencing. The clinical care and those who are responsible for data collection are blind to the patients groups and the type of drugs.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9195965919

Approval date
2019-05-28, 1398/03/07

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.691

Health conditions studied

1

Description of health condition studied
Gastrointestinal bleeding

ICD-10 code
T47.8

ICD-10 code description
Other agents primarily affecting the gastrointestinal system

2

Description of health condition studied
Ventilator-associated pneumonia

ICD-10 code
J84.9

ICD-10 code description
Interstitial pulmonary disease, unspecified

Primary outcomes

1

Description
The rate of ventilator-associated pneumonia

Timepoint
48 hours after intervention

Method of measurement
chest radiograghy

2

Description

The rate of gastrointestinal bleeding

Timepoint

48 hours after intervention

Method of measurement

Blood in stool and vomit

Secondary outcomes

1

Description

Upper airway colonization

Timepoint

48 hours after intervention

Method of measurement

Microbiological culture

2

Description

Hospital stay in the intensive care unit

Timepoint

After intervention

Method of measurement

Questionnaire

3

Description

The rate of mortality

Timepoint

After intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group 1: Who will receive 4 mg/kg/day of intravenous ranitidine 3 times per day.

Category

Prevention

2

Description

Intervention group 2: Who will receive 1 mg/kg/day of intravenous pantoprazole 2 times per day.

Category

Prevention

3

Description

Intervention group 3: Who will receive 60 mg/kg/day of oral sucralfate 4 times per day.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Children's Hospital

Full name of responsible person

Majid Sezavar

Street address

Akbar Children's Hospital, Shahid Kaveh 14, Shahid Kaveh Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9173595100

Phone

+98 51 3870 9225

Email

iomresearch@mums.ac.ir

2

Recruitment center

Name of recruitment center

Doctor Sheikh Hospital

Full name of responsible person

Majid Sezavar

Street address

Doctor Sheikh Hospital, Taheri Street, Tohid Square

City

Mashhad

Province

Razavi Khorasan

Postal code

71348714737

Phone

+98 51 3726 9021

Email

Sheikh.Hos@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Phone
+98 51 3841 1538
Email
vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Majid Sezavar
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Akbar Children's Hospital, Shahid Kaveh 14, Shahid Kaveh Boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
9173595100
Phone
+98 51 3870 9225
Email
sezavardm@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Sezavar
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Province
Razavi Khorasan
Postal code
9173595100
Phone
+98 51 3870 9225
Email
sezavardm@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Sezavar
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Akbar Children's Hospital, Shahid Kaveh 14, Shahid Kaveh Boulevard
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Email
sezavardm@mums.ac.ir

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
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Majid Sezavar provides the analysis code to the applicants via email: sezavardm@mums.ac.ir

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

Applicants can respond to the email of the respondent and receive a response within a week

Comments