# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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

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iomresearch@mums.ac.ir

### 2

**Recruitment center**

**Name of recruitment center**

Doctor Sheikh Hospital

**Full name of responsible person**

Majid Sezavar

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Doctor Sheikh Hospital, Taheri Street, Tohid Square

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

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

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1394491388

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+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
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

**Contact**
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Mashhad University of Medical Sciences
**Full name of responsible person**
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**Position**
Assistant Professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
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**Postal code**
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**Phone**
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## 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**