

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Clinical trial for comparing standard treatment for non-variceal upper GI bleeding with and without Octreotide in pediatrics

Protocol summary

Study aim

evaluating the effect of adding Octreotide to the treatment in reducing GI bleeding

Design

Randomized double blind placebo-controlled clinical trial

Settings and conduct

Fifty patients aged 0-15 years with gastrointestinal bleeding will be recruited in the study regarding inclusion and exclusion criteria. The patients will be admitted to Mofid children hospital and will receive the therapeutic dose of Pantoprazole, then will be randomly divided into two intervention and control groups; in the intervention group, patients will receive 1 to 2 µg / kg octreotide, and in the control group, placebo will be prescribed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of GI bleeding, age under 15 years, hemodynamic stability. Exclusion criteria: abnormal levels of liver enzymes and bilirubin, variceal gastrointestinal bleeding, a known case of gastrointestinal varices, hepatomegaly or splenomegaly in the evaluation, chronic liver disease grade C in child pugh score.

Intervention groups

Intervention group: receiving the therapeutic dose of Pantoprazole and 1 to 2 µg / kg octreotide, Control group: receiving the therapeutic dose of Pantoprazole and placebo.

Main outcome variables

hemoglobin range during treatment, need of receiving blood, rebleeding during hospitalization

General information

Reason for update

Due to delay in preparing the placebo and getting authorization for using the injectable placebo, the study conducted by about one year delay.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009475N6**

Registration date: **2019-02-14, 1397/11/25**

Registration timing: **prospective**

Last update: **2020-07-06, 1399/04/16**

Update count: **1**

Registration date

2019-02-14, 1397/11/25

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

Vice Chancellor for research of Shahid Beheshti
University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2019-03-02, 1397/12/11

Actual recruitment end date

2019-12-31, 1398/10/10

Trial completion date

2020-01-31, 1398/11/11

Scientific title

Clinical trial for comparing standard treatment for non-

variceal upper GI bleeding with and without Octreotide in pediatrics	hospitalization, failure of treatment defined as a recurrence of bleeding or continuous bleeding during treatment will be recorded.
Public title comparing the effect of Octreotide on non-variceal GI bleeding in children	Secondary Ids empty
Purpose Treatment	Ethics committees <u>1</u> Ethics committee Name of ethics committee institutional ethics committee for Pharmacy, Nursing and midwifery schools Street address 2nd floor, School of Nursing and Midwifery, Valiasr and Niayesh junction City Tehran Province Tehran Postal code 1546815514 Approval date 2017-07-01, 1396/04/10 Ethics committee reference number IR.SBMU.PHNM.1396.734
Inclusion/Exclusion criteria Inclusion criteria: diagnosis of GI bleeding age under 15 years hemodynamic stability Exclusion criteria: abnormal levels of liver enzymes and bilirubin variceal gastrointestinal bleeding Known case of gastrointestinal varices Hepatomegaly or splenomegaly in evaluation chronic liver disease grade C in child pugh score	
Age To 15 years old	
Gender Both	
Phase 2	
Groups that have been masked • Participant • Care provider • Investigator • Outcome assessor • Data analyser	
Sample size Target sample size: 50 Actual sample size reached: 43	
Randomization (investigator's opinion) Randomized	
Randomization description the randomization has been performed using the permuted block randomization table.	
Blinding (investigator's opinion) Double blinded	
Blinding description The medication and placebo will be in look-alike coded packages, and the codes based on the permuted block randomization table will be provided to the researcher by a designated person via phone. At the end of the study, after organizing the data by the same person, the statistical expert will perform the analysis. Then, the code packet will be opened, and the final results will be reported.	Health conditions studied <u>1</u> Description of health condition studied Gastrointestinal bleeding in children ICD-10 code K29.01 ICD-10 code description Acute (erosive) gastritis with haemorrhage
Placebo Used	Primary outcomes <u>1</u> Description Stop gastrointestinal bleeding Timepoint every hour until bleeding stops Method of measurement gastric lavage
Assignment Parallel	
Other design features All patients will be visited by a physician and patients' demographic characteristics including Age, Sex, weight, height, co-morbidities, and clinical findings including coagulation status, gastrointestinal disease history, endoscopic findings, hemoglobin range during treatment, need of receiving blood, and also dose and duration of treatment with octreotide will be recorded. Also, duration of hospitalization, patient outcome, re-bleeding during	Secondary outcomes <u>1</u> Description Need for blood transfusion Timepoint 24 hours before until 48 hours after intervention Method of measurement

Volume of blood infusion (milliliter per kilogram)

2

Description

hemoglobin level

Timepoint

daily during admission

Method of measurement

complete blood count

Intervention groups

1

Description

Intervention group: patients will receive 1 to 2 micrograms of Octreotide per kilogram of body weight per hour until the cessation of bleeding. Every 50 micrograms will be infused in 50 milliliters of normal saline as a one milliliter per kilogram weight per hour.

Category

Treatment - Drugs

2

Description

Control group: patients will receive placebo ampule in 50 milliliters of normal saline infused as a 1 milliliter per kilogram weight per hour until the cessation of bleeding.

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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Tehran

Province

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1546815514

Phone

+98 21 2222 7029

Email

mirrahimi@yahoo.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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1985717443

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Email

mpd@sbm.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

Azin Hemmati

Position

Doctor of pharmacy

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Valiasr street, Niayesh junction.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Pejman Rouhani

Position

pediatric Gastroenterology

Latest degree

Subspecialist

Other areas of specialty/work

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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

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 be 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 be 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

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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City