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)

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+98 21 8820 0118

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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

Public title
comparing the effect of Octreotide on non-variceal GI bleeding in children
Purpose
Treatment
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.
Placebo
Used
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 hospitalization, failure of treatment defined as a recurrence of bleeding or continuous bleeding during treatment will be recorded.

Secondary Ids

empty

Ethics committees

1

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

Health conditions studied

1

Description of health condition studied
Gastrointestinal bleeding in children
ICD-10 code
K29.01
ICD-10 code description
Acute (erosive) gastritis with haemorrhage

Primary outcomes

1

Description
Stop gastrointestinal bleeding
Timepoint
every hour until bleeding stops
Method of measurement
gastric lavage

Secondary outcomes

1

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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1546815514
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+98 21 2222 7029
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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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Postal code
1985717443
Phone
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Email
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
Azin Hemmati
Position
Doctor of pharmacy
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
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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
Pediatrics

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Person responsible for updating data

Contact

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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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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