Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effectiveness of a single dose of ondansetron in reducing the need for hospitalization or intravenous fluid therapy in children with gastroenteritis

Protocol summary

Study aim
Determining the effectiveness of a single dose of ondansetron in reducing the need for hospitalization or IV fluid therapy in children with gastroenteritis

Design
The clinical trial has a control group with parallel groups, double-blind, randomized and on a total of 60 patients. In this study, simple randomization was used by creating a random sequence in Excel and hiding it for the researcher.

Settings and conduct
After randomization, children with gastroenteritis who refer to the emergency room of Imam Hossein Children's Hospital and meet the inclusion and exclusion criteria are assigned to one of the two drug intervention or control groups. The control group will be given a placebo and the intervention group will be given medication to control vomiting and start oral fluid therapy. The doctor and the patients are not aware that they have received the drug or the placebo. Up to 4 hours after the start of oral fluid therapy, the patient will be monitored for the main outcomes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children 6 months to 6 years with acute non-bloody diarrhea with mild to moderate dehydration and vomiting in the last 4 hours Exclusion criteria: Severe shock and dehydration and the presence of surgical reasons for vomiting

Intervention groups
Patients are placed in two groups of 30 people randomly. The control group receives placebo and the intervention group receives ondansetron. Both groups receive other standard treatments for diarrhea, including oral fluid therapy and zinc syrup, and advice on warning signs.

Main outcome variables
repeated vomiting; tolerance of oral fluid therapy; need for hospitalization; The need for intravenous fluid therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220128053852N1**
Registration date: **2023-03-04, 1401/12/13**
Registration timing: **prospective**

Last update: **2023-03-04, 1401/12/13**
Update count: **0**

Registration date
2023-03-04, 1401/12/13

Registrant information

Name
Minoo Saeidi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3386 6266

Email address
minoo.saeidi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-21, 1402/01/01

Expected recruitment end date
2023-06-20, 1402/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of a single dose of ondansetron in reducing the need for hospitalization or intravenous fluid therapy in children with gastroenteritis

Public title
Ondansetrin in pediatruc Gastroentritis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 6 and 60 months At least once watery and loose diarrhea in 24 hours Vomiting at least once in the last 4 hours Patients with mild to moderate dehydration

Exclusion criteria:
Severe dehydration or hypovolemic shock Surgical causes of vomiting Adverse drug reaction to Ondansetron Bloody vomiting Severe abdominal distention or ileous Congenital or aquired cardiac diseases Under 6 months infants Bloody stool

Age
From **6 months** old to **60 months** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
we will use blocked randomisation. Using the Random Allocation software 2.0, for 2 study groups, 10 blocks of 6 were calculated for a sample size of 60 people, and each person will be identified with a unique code (consisting of two letters and a Latin number). To assign the child to each of the 2 study groups, an envelope containing a unique code and treatment group will be delivered to the child's parents. The associate nurse of the plan, who is stationed next to the nurse in charge of fluid therapy, will open the envelope and determine the type of intervention before the patient's admission.

Blinding (investigator's opinion)
Double blinded

Blinding description
We put ondansetron and placebo in identical packages and write code A or B on the package. As much as possible, the appearance of the medicine is not visible to the parents. Only the researcher is aware of which A and B are the intervention group and which is the control group, and the rest of the people involved, including the doctor and the person in charge of data analysis, are not aware.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences

Street address
Hezar jarib

City
Isfahan

Province
Isfehan

Postal code
8174602647

Approval date
2022-10-06, 1401/07/14

Ethics committee reference number
IR.MUI.MED.REC.1401.252

Health conditions studied

1

Description of health condition studied
Acute gastroentritis in children

ICD-10 code
A08.4

ICD-10 code description
Viral intestinal infection, unspecified

Primary outcomes

1

Description
The need for intravenous fluid therapy

Timepoint
During the first 4 hours of receiving the drug and placebo, the patient's symptoms are evaluated every hour

Method of measurement
Clinical judgment of the doctor and the degree of dehydration of the patient

Secondary outcomes

1

Description
Repeated vomiting

Timepoint

First 4 hours after intervention

Method of measurement

History taking

Intervention groups

1

Description

Control group: 5 cc of placebo that is as similar in appearance, color, and taste as possible to the original drug. The placebo drug will be prepared by the pharmacy of Dr. Sabzeqabaei, a member of the Faculty of Pharmacy Department of Isfahan Pareshki University of Sciences, and it will be prepared as a solution with the color, smell, and consistency as similar as possible to the original drug.

Category

Placebo

2

Description

Intervention group: Fifteen hundred milligrams per kilogram of the patient's weight of Andasterone is taken orally for one dose. Ondansetron Syrup is a product of Exir Pharmaceutical Company and contains 4 mg of drug per 5 cc of solution.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Children's Hospital

Full name of responsible person

Minoo Saeidi

Street address

Imam Khomeini

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Email

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Web page address

https://mui.ac.ir/en

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Minoo Saeidi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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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
All data after de-identification
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Scientific institutions
Under which criteria data/document could be used
Academic uses by faculty colleagues of universities in Iran or other universities in the world
From where data/document is obtainable
Email to the research officer at minoo.saeidi@gmail.com
What processes are involved for a request to access data/document
Email to the research officer And making decisions depending on the conditions and agreement
Comments