

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

Phone

+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

Ondansetron in pediatric Gastroenteritis

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 ileus Congenital or acquired 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

Isfahan

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 gastroenteritis 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

City

Isfahan

Province

Isfahan

Postal code

8195163381

Phone

+98 31 3386 6266

Fax

+98 31 3386 8286

Email

emamhossein_hospital@mui.ac.ir

Web page address

http://www.ehuch.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Minoo Saeidi

Street address

Hezar jarib

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

minoo.saeidi@gmail.com

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

Street address

Isfahan university of medical sciences

City

Isfahan

Province

Isfahan

Postal code

8174602647

Phone

+98 31 3668 0048

Email
minoo.saeidi@gmail.com

Person responsible for scientific 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
Street address
Hezar jarib
City
Isfahan
Province
Isfahan
Postal code
8174602647
Phone
+98 31 3668 0048
Email
minoo.saeidi@gmail.com

Person responsible for updating data

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
Street address

Hezar jarib
City
Isfahan
Province
Isfahan
Postal code
8174602647
Phone
+98 31 3668 0048
Email
minoo.saeidi@gmail.com

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