

# 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

Minoos 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

Minoos 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

Minoos 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

Minoos 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

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**Postal code**  
8174602647

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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