

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the effect of oral Ondansetron vs intramuscular injection in reducing vomiting in Children with acute gastroenteritis referred to pediatric emergency department

Protocol summary

Summary

Acute gastroenteritis is one of the most common complaints in children referred to the emergency department. In the disease, vomiting can lead to dehydration, electrolyte disturbances, and even hospitalization. Ondansetron is one of the drugs used to treat vomiting. The aim of this study is to compare the effect of ondansetron in reducing vomiting by oral and intramuscular administration methods. This study is a randomized double-blind clinical trial. In the study, 100 children aged 1-10 years old with acute gastroenteritis that referred to Bahrami Children's Hospital in Tehran, were enrolled. The inclusion criteria: Children aged 1 to 10 years with acute gastroenteritis and mild to moderate dehydration. The exclusion criteria: The presence of any chronic disease or alarm sign or symptoms such as headache or abdominal distention. The children were divided in two groups in a simple randomized method. The first group was given oral Ondansetron (manufactured by Iranian company, World Health Company) with dose 0.2 mg/kg. The second group received intramuscular injection of ondansetron (manufactured by Iranian company, Tehran Chemistry Company) with dose 0.2 mg/kg. Oral fluid therapy begins 30 minutes after receiving the drug. If the child has been tolerated, the treatment is successful and he/she is monitored to up four hours in the emergency department. If there was no vomiting after 4 hours, they will be discharged. Patients were followed up by telephone 48 hours after starting treatment. During this study, they are evaluated for the side effects of ondansetron, including vomiting, headache, and tachycardia. If they had no oral tolerate, they would be hospitalized and treated intravenously rehydration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082118971N5**

Registration date: **2017-09-15, 1396/06/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-15, 1396/06/24

Registrant information

Name

Kambiz Eftekhari

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 7301 3000

Email address

k-eftekhari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of oral Ondansetron vs intramuscular injection in reducing vomiting in Children with acute gastroenteritis referred to pediatric emergency department

Public title

Comparison of the effect of oral ondansetron vs intramuscular injection on vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria: Children aged 1 to 10 years with acute gastroenteritis and mild to moderate dehydration; The vomiting has started in the last 24 hours; There is at least one episode of vomiting, within the last 6 hours; The disease is feverless or has a mild fever (below 38 ° C of axillary). The exclusion criteria: Children who have received any antiemetic drugs within the last 6 hours; The presence of any chronic disease or alarm sign or symptoms such as headache or abdominal distention; There is severe dehydration or shock; Diarrhea is intense and has a frequency of more than once per hour; The patient has a history of any hypersensitivity to 5-HT3 receptor antagonists.

Age

From **1 year** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Bahrami Children's Hospital

City

TEHRAN

Postal code

1641744991

Approval date

2017-05-31, 1396/03/10

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2713

Health conditions studied

1

Description of health condition studied

Viral intestinal infection, unspecified

ICD-10 code

A08.4

ICD-10 code description

Viral intestinal infection, unspecified

Primary outcomes

1

Description

Vomiting

Timepoint

30 minutes after receiving ondancetron, then 4 hours later in the emergency department, then 48 hours after the administration of drug in home.

Method of measurement

Direct view and parent question

2

Description

Require hospitalization

Timepoint

30 minutes after receiving ondancetron, then 4 hours later in the emergency department, then 48 hours after the administration of drug in home.

Method of measurement

Direct view and parent question

Secondary outcomes

1

Description

Headache

Timepoint

4 hours after receiving ondancetron in the emergency department

Method of measurement

In children older than 4 years of age, through questions from the children and their parents. In children younger than 4 years, there is an increase in restlessness and irritability through direct observation and asking from their parents.

2

Description

Tachycardia

Timepoint

4 hours after receiving ondancetron in the emergency department

Method of measurement

Using auscultation by therapist with stethoscope. In children 1-3 years, the pulse rate more than 150 beats per minute, in 4 - 5 years old more than 135, in 6 - 8 years old more than 130 and in 8 - 10 years old more than 110 are abnormal and considered to be tachycardia.

Intervention groups

1

Description

The children were divided in two groups in a simple randomized method. The first group was given oral Ondansetron (manufactured by Iranian company, World Health Company) with dose 0.2 mg/kg. Oral fluid therapy begins 30 minutes after receiving the drug. If the child has been tolerated, the treatment is successful and he/she is monitored to up four hours in the emergency department. If there was no vomiting after 4 hours, they will be discharged. Patients were followed up by telephone 48 hours after starting treatment.

Category

Treatment - Drugs

2

Description

The second group received intramuscular injection of Ondansetron (manufactured by Iranian company, Tehran Chemistry Company) with dose 0.2 mg/kg. Oral fluid therapy begins 30 minutes after receiving the drug. If the child has been tolerated, the treatment is successful and he/she is monitored to up four hours in the emergency department. If there was no vomiting after 4 hours, they will be discharged. Patients were followed up by telephone 48 hours after starting treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami Children's Hospital

Full name of responsible person

Kambiz Eftekhari

Street address

Kiaee Street, Damavand Street

City

TEHRAN

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhondzadeh

Street address

Tehran University of Medical Sciences

City

TEHRAN

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Bahrami Children's Hospital

Full name of responsible person

Kambiz Eftekhari

Position

Assistant professor of pediatric Gastroenterology

Other areas of specialty/work

Street address

Bahrami Children's Hospital

City

TEHRAN

Postal code

1641744991

Phone

+98 21 7301 3000

Fax

Email

k-eftekhari@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bahrami Children's Hospital

Full name of responsible person

Kambiz Eftekhari

Position

Assistant professor of Pediatric Gastroenterology

Other areas of specialty/work

Street address

Bahrami Children's Hospital

City

TEHRAN

Postal code

1641744991

Phone

+98 21 7301 3000

Fax

Email

k-eftekhari@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Bahrami Children's Hospital

Full name of responsible person

Kambiz Eftekhari

Position

Assistant professor of Pediatric Gastroenterology

Other areas of specialty/work

Street address

Bahrami Children's Hospital

City

TEHRAN

Postal code

1641744991

Phone

+98 21 7301 3000

Fax

Email

k-eftekhari@sina.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty