Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of oral Ondansetron on Decreasing the Vomiting Associated With Acute Gastroenteritis in pediatrics

Protocol summary

Summary

The goal of this trial is to compare the effect of oral ondansetron with placebo, in treatment of vomiting due to acute gastroenteritis in infants and children (treatment with oral rehydration therapy and based on WHO protocol). A total of 176 patients with simple acute gastroenteritis, aged between 1 and 10 years, will be included. In a double blind fashion, the patients will be randomized to receive oral ondansetron or placebo tablets (Dosage of drug will be set based on weight of children). 30 minutes after administration, ORS will be prescribed (based on age and weigh of patient and based on WHO protocol). If no vomiting occurs during 4 hours of ORT, treatment has been successful, but if vomiting continues, treatment is not successful and patient will go on treatment based on hospital protocol. After 4 hours, the patient will be evaluated again and discharged based on WHO guidelines. After 48 hours, incidence of possible vomiting will be asked by telephone.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710221545N1**
Registration date: **2011-02-26, 1389/12/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-02-26, 1389/12/07

Registrant information

Name
Hamidreza Badeli
Name of organization / entity
Guilan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 13 1322 9523
Email address
badeli@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2010-12-22, 1389/10/01

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral Ondansetron on Decreasing the Vomiting Associated With Acute Gastroenteritis in pediatrics

Public title

Effect of oral Ondansetron on Decreasing the Vomiting Associated With Acute Gastroenteritis in pediatrics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 1 to 10 years old, Simple acute gastroenteritis, mild to moderate dehydration, Onset of disease in 24 hours prior to the study, At least one episode of vomiting in 6 hours ago, no fever or low grade fever Exclusion criteria: infants and children that use any antivomiting drugs, Any chronic disease, Alarm signs such as headache or abdominal distension, Severe

dehydration or shock, Sever diarrhea more than one episode in an hour, Any previous unfavorable response to 5HT3 receptor inhibitor drugs, Any situation that ORT is not recommended

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **176**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice Chancellor for research, Guilan University of Medical Sciences

Street address
Vice Chancellor for research, Guilan University of Medical Sciences, Mellat Street, Namjoo Avenue

City
Rasht

Postal code

Approval date
2010-09-28, 1389/07/06

Ethics committee reference number
10229

Health conditions studied

1

Description of health condition studied
Acute gastroenteritis

ICD-10 code
A09

ICD-10 code description
Diarrhoea and gastroenteritis of presumed infectious origin

Primary outcomes

1

Description
Vomiting

Timepoint
4 hours and 48 hours after oral ondansetron administration

Method of measurement
Direct inspection and asking patient`s parents

Secondary outcomes

1

Description
Bradycardia

Timepoint
4 hors after oral ondansetron administration

Method of measurement
Physical examination

2

Description
Skin rash

Timepoint
4 hors after oral ondansetron administration

Method of measurement
Physical examination

3

Description
Tachycardia

Timepoint
4 hors after oral ondansetron administration

Method of measurement
Physical examination

4

Description
Headache

Timepoint
4 hors after oral ondansetron administration

Method of measurement
History

5

Description
diarrhea

Timepoint
4 hours after oral ondansetron administration

Method of measurement
History

Intervention groups

1

Description
Ondansetron tablets, 30 minutes before ORT, with dosage adjusting based on patient`s weight (Using ondansetron 4 mg tablets)
Category
Treatment - Drugs

2

Description
Placebo tablets, 30 minutes before ORT
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
17 Shahrivar Hospital of Rasht
Full name of responsible person
Street address
17 Shahrivar Hospital- Namjoo st
City
Rasht

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research, Guilan University of Medical Sciences
Full name of responsible person
Dr. Abdolrasol Sobhani
Street address
Vice Chancellor for research, Guilan University of Medical Sciences, Mellat Street, Namjoo Avenue
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research, Guilan 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
17 shahrivar hospital
Full name of responsible person
Hamidreza Badeli
Position
Pediatric Nephrologist,Assistant Professor
Other areas of specialty/work
Street address
17 shahrivar Hospital. Namjoo street
City
Rasht
Postal code
Phone
+98 13 1322 9523
Fax
Email
badeli@gums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
17 shahrivar hospital
Full name of responsible person
Hamidreza badeli
Position
Pediatric Nephrologist,Assistant Professor
Other areas of specialty/work
Street address
17 shahrivar Hospital. Namjoo street
City
Rasht
Postal code
Phone
+98 13 1322 9523
Fax
Email
badeli@gums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Saman Rezaeian
Position
Medical Student
Other areas of specialty/work
Street address
Student
City
Rasht
Postal code

4138673557

Phone

Fax

Email

Saman8484@gmail.com

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