

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study of effect of oral dimenhydrinate in children with acute gastroenteritis

Protocol summary

Summary

Objectives: Determination of effect of oral dimenhydrinate in children with acute gastroenteritis, Design: This is a double-blind randomized clinical trial conducted on 200 children with gastroenteritis that patients referred to emergency ward of Mohammad Kermanshahi hospital. Setting and conduct: Patients were randomly assigned to two groups receiving dimenhydrinate and placebo groups. At 24 hours after the first administration of prescribed medication and after 7 to 14 days after discharge, the variables of interest are collected, Participants including major eligibility criteria: Diagnosis of acute gastroenteritis by Specialist Physicians, At least 5 episodes of vomiting in 12 Hours, Intervention: 4 doses of warfarin dose dimenhydrinate (1 mg / kg / dose to 50 mg / dose) or placebo for 4 doses during 6 days a week, main outcome variable: number of episodes of vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014083018974N1**

Registration date: **2015-03-02, 1393/12/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-02, 1393/12/11

Registrant information

Name

Simin Gheini

Name of organization / entity

Kermanshah University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

s.gheini@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences, Address: Vice chancellor for research, Building No. 2 of Kermanshah University of Medical Sciences, Shahidbeheshti Bolvar

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of effect of oral dimenhydrinate in children with acute gastroenteritis

Public title

Effects of dimenhydrinate in children with acute gastroenteritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Diagnosis of acute gastroenteritis by Specialist Physicians, At least 5 episodes of vomiting in 12 Hours; Aged between 1 to 12 years. Exclusion criteria: Chronic medical conditions of pre-existing such as gastrointestinal disease; malignancy; metabolic; cardiac; endocrine and metabolism, immune or nervous disorder. Secondary diagnosis of suspected from abdominal

surgery or Or gynecologic conditions, urinary tract infections; migraine or meningitis. The use of antiemetic therapy in the 48 hours before the visit to the emergency. Use of other drugs such as acetaminophen or ibuprofen in the last 48 hours. History of allergies or adverse reactions to dimenhydrinate. Severe loss of water and requires urgent treatment with intravenous fluids. Hematemesis or hematochezia.

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **200**

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**

Kermanshah University of Medical Sciences Ethics Committee

Street address

Kermanshah University of Medical Sciences, Shahid Beheshti Bolvar, Kermanshah

City

Kermanshah

Postal code**Approval date**

2013-12-17, 1392/09/26

Ethics committee reference number

40602

Health conditions studied**1****Description of health condition studied**

acute gastroenteritis

ICD-10 code

K52.9

ICD-10 code description

Noninfective gastroenteritis and colitis, unspecified

Primary outcomes**1****Description**

The number of vomiting episodes

Timepoint

Within 24 hours after using the first dose of prescription medication

Method of measurement

visit

Secondary outcomes**1****Description**

The number of episodes of diarrhea

Timepoint

Within 24 hours after using the first dose of prescription medication

Method of measurement

visit

Intervention groups**1****Description**

Dimenhydrinate 4 doses (1mg/kg dose max 200 mg/dose)

Category

Treatment - Drugs

2**Description**

placebo doses (1 mg / kg / dose to 50 mg / dose) during 6 days per week

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mohammad Kermanshahi Hospital

Full name of responsible person

Ameli Somayeh

Street address

Mohammad Kermanshahi Hospital, HelalAhmar, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Vice chancellor for research, Building No. 2 of Kermanshah University of Medical Sciences, Shahidbeheshti Bolvar

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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, Kermanshah 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**

Kermanshah university of medical sciences

Full name of responsible person

Reza Akramipour

Position

Chief of Department of Pediatrics

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Full name of responsible person

dr somayeh Ameli

Position

Rezident of Pediatric

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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