

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Pyridoxine(Vitamin B6) in control of vomiting due to acute gastroenteritis in children 6 month to 12 years

Protocol summary

Summary

Vomiting due to gastroenteritis can cause some complications. Various drugs used for treatment of vomiting. In pediatrics there is no evidence for treatment of vomiting with pyridoxine. This study reviews the effect of pyridoxine in treatment of acute gastroenteritis in children. This study is single blind randomized clinical trial with placebo and single center. Children admitted with gastroenteritis in Amirkabir hospital from August to December 2011 and had inclusion criteria placed in case and control group. Sample size is 140. Control group will treat with parenteral rehydration and placebo (distilled water). Case group will treat with parenteral rehydration and parenteral pyridoxine. Frequency of vomiting and other symptoms collect with checklist from admission until third day. Response to treatment compares in case and control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108167342N1**

Registration date: **2012-01-17, 1390/10/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-01-17, 1390/10/27

Registrant information

Name

Farshad Jafari

Name of organization / entity

Arak University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 86 1313 5378

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences and Health Services

Expected recruitment start date

2011-09-11, 1390/06/20

Expected recruitment end date

2012-01-10, 1390/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Pyridoxine(Vitamin B6) in control of vomiting due to acute gastroenteritis in children 6 month to 12 years

Public title

Effect of Pyridoxine(Vitamin B6) in control of vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.6 month to 12 years old child. 2.Acute viral gastroenteritis with vomiting. 3.No treatment before admission. 4.Completed consent form. Exclusion criteria: 1.Severe dehydration. 2.Abnormal finding in stool exam (RBC, WBC, parasite). 3.Acute abdomen. 4.Patient withdrew from the project. 5.Discharge the patient with personal satisfaction.

Age

To **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Arak University of Medical Sciences

Street address

Vice Chancellor for Research, Arak University of Medical Sciences, Pardis site, Basij Square, Arak, Iran

City

Arak

Postal code

3848176941

Approval date

2011-09-05, 1390/06/14

Ethics committee reference number

90-112-4

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

Vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

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

Frequency of vomiting

Timepoint

8 hour before admission,first day,second day,third day of admission

Method of measurement

Frequency of vomiting with questionnaire

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

dayes of admission

Timepoint

day

Method of measurement

dayes of admission with quetionnaire

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

Case group: pyridoxine 2mg/kg (max 60 mg) IV, stat, at admission. Frequency of vomiting and days of admission are calculated.

Category

Treatment - Drugs

2**Description**

Control group: parenteral rehydration with placebo (1 ml distilled water) IV at admission. Frequency of vomiting and days of admission are calculated.

Category

Placebo

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

Amirkabir Hospital

Full name of responsible person

Parsa Yousefi,Farshad Jafari

Street address

Vice Chancellor for Education of AmirKabir Hospital

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Said Changizi Ashtiani

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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

Arak 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**

Arak University of Medical Sciences and Health Services research

Full name of responsible person

Parsa Yousefi

Position

Assistant Professor, Pediatrics Nephrologist

Other areas of specialty/work**Street address**

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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