

# 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)

###### Phone

+98 86 1313 5378

###### Email address

farshadjafari@arakmu.ac.ir

###### 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

days of admission

#### Timepoint

day

#### Method of measurement

days of admission with questionnaire

## 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

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Said Changizi Ashtiani

##### Street address

Vice Chancellor for Research, Arak University of

Medical Sciences, Pardis site, Basij Square, Arak, Iran

**City**

Arak

**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

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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*