

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Study of the effect of vitamin A supplement in the treatment of acute Gastroenteritis in children 1-5 year

#### Protocol summary

##### Study aim

Study of the effect of vitamin A supplement in the treatment of acute Gastroenteritis in children 1-5 year

##### Design

This study is a one-blinded clinical trial. The study population will be all patients referred to Mohammad Kermanshahi Hospital of Kermanshah. 50 eligible patients will be selected conveniently and randomly assigned to two intervention and control groups.

##### Settings and conduct

This study that will be conducted in Mohammad Kermanshahi Hospital of Kermanshah is a one-blinded one that the data analyzer was kept blind to the allocation of study groups. Both groups will receive drug and placebo equivalents and the results will be compared.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 1 and 5 years; Children with acute diarrhea and vomiting  
Exclusion criteria: Immunodeficiency patients and patients with allergy to bovine protein and lactose; Patients with chronic diarrhea and diarrhea caused by diseases (celiac-cystic fibrosis, etc.); Patients with drug-induced diarrhea; Patients with moderate to severe malnutrition

##### Intervention groups

The intervention group will receive 25,000 units of oral vitamin A twice daily for 4 days in addition to routine treatment. The control group will receive 25,000 units of distilled water twice daily for 4 weeks in addition to the routine treatment.

##### Main outcome variables

The number of vomiting episodes; The number of episodes of diarrhea

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N140**

Registration date: **2020-02-23, 1398/12/04**

Registration timing: **prospective**

Last update: **2020-02-23, 1398/12/04**

Update count: **0**

##### Registration date

2020-02-23, 1398/12/04

##### Registrant information

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-29, 1398/12/10

##### Expected recruitment end date

2020-04-29, 1399/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of the effect of vitamin A supplement in the treatment of acute Gastroenteritis in children 1-5 year

##### Public title

Study of the effect of vitamin A supplement in the treatment of acute Gastroenteritis in children 1-5 year

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Age between 1 and 5 years Children with acute diarrhea and vomiting

#### **Exclusion criteria:**

Immunodeficiency patients and patients with allergy to bovine protein and lactose Patients with chronic diarrhea and diarrhea caused by diseases (celiac-cystic fibrosis, etc.) Patients with drug-induced diarrhea Patients with moderate to severe malnutrition

### **Age**

From **1 year** old to **5 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

- Data analyser

### **Sample size**

Target sample size: **50**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Using the random number table, patients are divided into two groups of 25. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the control group.

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

In this study, the data analyzer was kept blind to the allocation of study groups.

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

##### **Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for

Research Affairs, Kermanshah University of Medical Sciences

### **City**

Kermanshah

### **Province**

Kermanshah

### **Postal code**

6715847141

### **Approval date**

2020-02-04, 1398/11/15

### **Ethics committee reference number**

IR.KUMS.REC.1398.1054

## **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**

Beginning and end of study

#### **Method of measurement**

Based on doctor observation and patient questions

### 2

#### **Description**

The number of episodes of diarrhea

#### **Timepoint**

Beginning and end of study

#### **Method of measurement**

Patient questions

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

The intervention group will receive 25,000 units of oral vitamin A twice daily for 4 days in addition to routine treatment.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

The control group will receive 25,000 units of distilled water twice daily for 4 weeks in addition to the routine treatment

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mohammad Kermanshahi Hospital

**Full name of responsible person**

Mohamadsaleh Kamrani

**Street address**

Helal Ahmar Crossroad, Mohammad Kermanshahi Hospital

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6713733135

**Phone**

+98 83 3721 8202

**Email**

mitra\_hemmati@Yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Farid Najafi

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

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**Province**

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6715847141

**Phone**

+98 83 3836 0014

**Email**

fnajafi@kums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kermanshah University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mohamadsaleh Kamrani

**Position**

Resident of Child

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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Helal Ahmar Crossroad, Mohammad Kermanshahi Hospital

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6713733135

**Phone**

+98 83 3721 8202

**Email**

mitra\_hemmati@Yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Mitra Hemmati

**Position**

Member of Kermanshah University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

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mitra\_hemmati@Yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mohamadsaleh Kamrani

**Position**

Resident of Child

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

**Street address**

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Hospital

**City**

Kermanshah

**Province**

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**Postal code**

6713733135

**Phone**

+98 83 3721 8202

**Email**

mitra\_hemmati@Yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The main outcomes of the study will be shared.

**When the data will become available and for how long**

4 months

**To whom data/document is available**

If requested, results will be made available to other academic researchers

**Under which criteria data/document could be used**

Collected data is confidential and will not be shared with anyone else

**From where data/document is obtainable**

To receive the documentation, email send for update manager

**What processes are involved for a request to access data/document**

In a 15-day period, the documents will be sent e-mail

**Comments**