

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Sep 2026

### The evaluation of the effect of vitamin A on watery diarrhea in children between 1-5 years old

#### Protocol summary

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##### Summary

This study is a clinical trial on 200 children aged 1-5 years. Patients admitted with complaints of acute watery diarrhea in Beheshti Hospital with the following characteristics are enrolled: Aged 1-5 years- With out dysentery that is confirmed by stool exam- Children with axillary temperature  $\geq 38^{\circ}$  are excluded from the study. Patients randomly assign into two groups (experiment or control). Experimental group receive one dose Intramuscular vitamin A 1000 IU/kg. The control group will not receive vitamin A. In both groups, treatment protocols for watery acute diarrhea shall be conducted. Frequency and duration of diarrhea within the past 24 hours is recorded by asking mothers

##### Recruitment status

**Recruitment complete**

##### Funding source

Kashan University of Medical Sciences

##### Expected recruitment start date

2012-11-05, 1391/08/15

##### Expected recruitment end date

2013-11-03, 1392/08/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012102411145N2**

Registration date: **2012-11-10, 1391/08/20**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-11-10, 1391/08/20

##### Registrant information

###### Name

Mohammad Reza Sharif

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5554 0026

###### Email address

##### Scientific title

The evaluation of the effect of vitamin A on watery diarrhea in children between 1-5 years old

##### Public title

The evaluation of the effect of vitamin A on watery diarrhea in children between 1-5 years old

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Children hospitalized with acute gastroenteritis in Shahid Beheshti hospital; Aged 1 - 5 years. exclusion criteria: Dysentery confirmed by stool exam; Axillary temperature equal to or more than  $38^{\circ}$  C; Underlying disease that can not be given injections of vitamin A.

##### Age

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

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

**Sample size**  
Target sample size: **200**

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

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**  
Kashan University of Medical Sciences

**Street address**  
5th Km of Ghotbe Ravandi Bulv.

**City**  
Kashan

**Postal code**

**Approval date**  
2012-10-27, 1391/08/06

**Ethics committee reference number**  
1/2892//29/5/پ

## Health conditions studied

1

**Description of health condition studied**  
Acute Watery Diarrhea

**ICD-10 code**  
A09.9

**ICD-10 code description**  
Gastroenteritis and colitis of unspecified origin

## Primary outcomes

1

**Description**  
Stop Diarrhea

**Timepoint**  
Daily

**Method of measurement**  
Study of records & asking from mother

2

**Description**  
Frequency of Diarrhea

**Timepoint**  
Daily

**Method of measurement**  
Study of records & asking from mother

### 3

**Description**  
Duration of diarrhea

**Timepoint**  
Daily

**Method of measurement**  
Study of records & asking from mother

## Secondary outcomes

1

**Description**  
Admission period

**Timepoint**  
Days of admission

**Method of measurement**  
Days recorded in dossier

## Intervention groups

1

**Description**  
Intervention: intramuscular injection of Vitamin A 1000 IU/kg

**Category**  
Treatment - Drugs

2

**Description**  
Control group: without Vitamin A

**Category**  
Treatment - Drugs

## Recruitment centers

1

**Recruitment center**

**Name of recruitment center**  
Beheshti Hospital

**Full name of responsible person**  
Dr. Mehrdad Hossein pour

**Street address**

**City**  
Kashan

## Sponsors / Funding sources

1

**Sponsor**  
**Name of organization / entity**

Kashan University of Medical Sciences  
**Full name of responsible person**  
 Dr. Gholam Ali Hamidi  
**Street address**  
 5th Kilometer Ghotbe Ravandi Bulv.Kashan University  
 of Medical Sciences  
**City**  
 kashan  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor  
 organization/entity?**  
 Yes  
**Title of funding source**  
 Kashan 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

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
 Kashan University of Medical Sciences  
**Full name of responsible person**  
 Dr.Mohammad Reza Sharif  
**Position**  
 Assistant Professor, Pediatric Infectious Diseases  
 Subspecialist  
**Other areas of specialty/work**  
**Street address**  
 5th Kilometer Ravand Bulv. Beheshti Hospital

**City**  
 Kashan  
**Postal code**  
**Phone**  
 +98 36 1555 0026  
**Fax**  
**Email**  
 mrsharifmd@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
 Kashan University of Medical Sciences  
**Full name of responsible person**  
 Dr.Mohammad Reza Sharif  
**Position**  
 Assistant Professor, Pediatric Infectious Diseases  
 Subspecialist  
**Other areas of specialty/work**  
**Street address**  
**City**  
**Postal code**  
**Phone**  
 00  
**Fax**  
**Email**  
**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