

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

sharif_m@kaums.ac.ir

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° 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