

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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		Research Affairs, Kermanshah University of Medical Sciences	
Purpose	Treatment	City	Kermanshah
Inclusion/Exclusion criteria		Province	Kermanshah
Inclusion criteria:	Age between 1 and 5 years Children with acute diarrhea and vomiting	Postal code	6715847141
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	Approval date	2020-02-04, 1398/11/15
Age	From 1 year old to 5 years old	Ethics committee reference number	IR.KUMS.REC.1398.1054
Gender	Both	Health conditions studied	
Phase	2-3	1	
Groups that have been masked	Data analyser	Description of health condition studied	
Sample size	Target sample size: 50	ICD-10 code	
Randomization (investigator's opinion)	Randomized	ICD-10 code description	
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.	Acute gastroenteritis	
Blinding (investigator's opinion)	Single blinded	Primary outcomes	
Blinding description	In this study, the data analyzer was kept blind to the allocation of study groups.	1	
Placebo	Used	Description	
Assignment	Parallel	Timepoint	
Other design features		Method of measurement	
Secondary Ids	empty	The number of vomiting episodes	
Ethics committees		2	
1		Description	
Ethics committee		Timepoint	
Name of ethics committee	Ethics committee of Kermanshah University of Medical Sciences	Method of measurement	
Street address	Building No.2, Shahid Beheshti, Vice Chancellor for	Based on doctor observation and 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

City

Kermanshah

Province

Kermanshah

Postal code

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

City

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Province

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Postal code

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Phone

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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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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

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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