

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of honey on duration of acute diarrhea in children

Protocol summary

Summary

This study is a clinical trial on 150 children aged 1-5 years admitted to pediatric clinic in Kashan Beheshti Hospital with complaints of acute watery diarrhea. Children with high fever ($T > 38.5^{\circ}\text{C}$), severe dehydration, bloody diarrhea, severe malnutrition, using of antibiotics, anti-diarrheal or anti-fungal drugs and patients with more than one complain or Immune deficiency are excluded from the study. Patients randomly assign into three groups. Experimental group1 receive honey prepared by Mahram Company 50 ml/1 liter ORS for 3 days and experimental group 2 receive honey prepared by Mahram Company 5 ml every 8 hours for 3 days and the control group will receive no honey. In three groups, treatment protocols for acute watery diarrhea (using ORS) shall be conducted. Frequency and duration of diarrhea within the past 24 hours is recorded by asking mothers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030911145N14**

Registration date: **2015-05-19, 1394/02/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-05-19, 1394/02/29

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

sharif_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of honey on duration of acute diarrhea in children

Public title

The effect of honey on acute diarrhea in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children admitted to pediatric clinic in Kashan Beheshti Hospital with complaints of acute watery diarrhea; Aged 1-5 years Exclusion criteria: High fever ($T > 38.5^{\circ}\text{C}$); Severe dehydration; Bloody diarrhea; Severe malnutrition; Using of antibiotics, anti-diarrheal or anti-fungal drugs; Patients with more than one complain; Immune deficiency

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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

Kashan University of Medical Sciences, Ghotbe
Ravandi Blvd, Kashan, Iran

City

Kashan

Postal code

Approval date

2015-04-29, 1394/02/09

Ethics committee reference number

KAUMS.REC.1394.012

Health conditions studied

1

Description of health condition studied

Acute diarrhea

ICD-10 code

A09.9

ICD-10 code description

Gastroenteritis and colitis of unspecified origin

Primary outcomes

1

Description

Duration of diarrhea

Timepoint

Daily

Method of measurement

Stool chart

2

Description

Frequency of diarrhea

Timepoint

Daily

Method of measurement

Counting the number of stools

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Oral administration of honey, 50
ml/1 liter ORS for 3 days

Category

Treatment - Drugs

2

Description

Intervention group 2: Oral administration of honey 5 ml
every 8 hours for 3 days plus ORS

Category

Treatment - Drugs

3

Description

Control group: Administration of ORS without honey

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Mohammad Reza Sharif

Street address

Shahid Beheshti Hospital, Ghotbe Ravandi Blvd,
Kashan, Iran

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

Kashan University of Medical Sciences, Ghotbe
Ravandi Blvd, Kashan, Iran

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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****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Sharif

Position

Associate Professor, Pediatric Infectious Diseases
Subspecialist

Other areas of specialty/work**Street address**

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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