

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The effect of *Thymus vulgaris* concentration on duration of acute diarrhea in children

Protocol summary

Summary

Objectives: To assess the effect of *Thymus vulgaris* concentration on the duration of diarrhea in children with acute watery diarrhea. Design: A double-blind randomized clinical trial. Setting and conduct: The eligible patients with complaints of diarrhea referred to Shahid Beheshti Hospital will be enrolled into the trial. Inclusion criteria: Age 1-5 years, Acute watery diarrhea. Exclusion criteria: High fever ($T > 38.5^{\circ}\text{C}$), Severe dehydration, Bloody diarrhea, Severe malnutrition, Using of antibiotics or anti-diarrheal drugs, Patients with more than one complain, Immune deficiency. Intervention group: Oral administration of *Thymus vulgaris* concentration 2.5 milliliters every 8 hours for 5 days plus ORS. Control group: Oral administration of placebo 2.5 milliliters every 8 hours for 5 days plus ORS. Primary outcome: Duration of diarrhea by asking from patient or mother, frequency of diarrhea by asking from patient or mother.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016123011145N19**

Registration date: **2017-02-27, 1395/12/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-27, 1395/12/09

Registrant information

Name

Mohammad Reza Sharif

Name of organization / entity

Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research and Technology, Kashan University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of *Thymus vulgaris* concentration on duration of acute diarrhea in children

Public title

The therapeutic effect of *Thymus vulgaris* concentration on acute diarrhea in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 1-5 years; Acute watery diarrhea

Exclusion criteria: High fever ($T > 38.5^{\circ}\text{C}$); Severe dehydration; Bloody diarrhea; Severe malnutrition; Using of antibiotics or anti-diarrheal 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: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kashan University of Medical Sciences

Street address

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

City

Kashan

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.KAUMS.REC.1395.136

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

Duration of diarrhea

Timepoint

Daily

Method of measurement

Asking from patient or mother

2

Description

Frequency of diarrhea

Timepoint

Daily

Method of measurement

Asking from patient or mother

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Oral administration of Thymus vulgaris concentration 2.5 milliliters every 8 hours for 5 days plus ORS.

Category

Treatment - Drugs

2

Description

Control group: Oral administration of placebo 2.5 milliliters every 8 hours for 5 days plus ORS.

Category

Placebo

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

Vice Chancellor of Research and Technology, 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
City
Kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research and Technology, 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

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Associate Professor, Pediatric Infectious Diseases
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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