

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 0026

##### Email address

sharif\_m@kaums.ac.ir

##### 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

**Name of organization / entity**  
Kashan University of Medical Sciences  
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**Position**  
Associate Professor, Pediatric Infectious Diseases Subspecialist  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**  
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**Other areas of specialty/work**  
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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