Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of Thymus vulgari concentration on duration of acute diarrhea in children

Protocol summary

Summary

Objectives: To assess the effect of Thymus vulgari 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°C), Severe dehydration, Bloody diarrhea, Severe malnutrition, Using of antibiotics or anti-diarrheall drugs, Patients with more than one complain, Immune deficiency. Intervention group: Oral administration of Thymus vulgari concentration 2.5 millliliters every 8 hours for 5 days plus ORS. Control group: Oral administration of placebo 2.5 millliliters 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)

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+98 31 5554 0026

Email address

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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 vulgari concentration on duration of acute diarrhea in children

Public title

The therapeutic effect of Thymus vulgari 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°C); Severe dehydration; Bloody diarrhea; Severe malnutrition; Using of antibiotics or anti-diarrheall 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 vulgari 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

Full name of responsible person
Dr. Mohammad Reza Sharif

Position
Associate Professor, Pediatric Infectious Diseases Subspecialist

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