

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects off Rheum ribes L. syrup on bloody diarrhea in children aged 12 to 72 months.

Protocol summary

Summary

The goal of this trial is to study Effects off Rheum ribes L. syrup on bloody diarrhea in children aged 12 to 72 months. Inclusion criteria: (1) age between 12 to 72 months; (2) history of passing loose stool (>3 times per day) mixed with blood and or mucus for ≤ 72 hours or >5 WBC in S/E, and (3) with or without the presence of fever, abdominal pain, anorexia, dehydration, and vomiting; (4) written, voluntary informed consents from the parent or legal guardians of the children were obtained at the time of admission. Exclusion criteria: (1) refusal of consent by parents; (2) treatment with an antimicrobial and or antidiarrheal agents within last 3 days; (3) fecal presence of erythrophagocytic trophozoite of Entameba histolytica or cyst/trophozoites of Giardia lamblia; (4) presence of concurrent illnesses (pneumonia, sepsis, meningitis, and toxic colitis). A Double - blind, Randomized, Controlled clinical trial. Ninety-four children aged 12 to 72 months with bloody dysentery caused by infection are either given a syrup base with or without Rheum ribes (n = 94) for 5 days; stool volume, frequency, excretion of blood/mucus, and relevant clinical and laboratory indices are determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070518356N1**
Registration date: **2014-08-28, 1393/06/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-28, 1393/06/06

Registrant information

Name

Ali Khiveh

Name of organization / entity

Shahid sadoughei University of Medical Sciences of Yazd

Country

Iran (Islamic Republic of)

Phone

+98 35 1724 0171

Email address

a-khivah@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Yazd Shahid Sadoghei University of Medical Sciences.

Expected recruitment start date

2014-08-06, 1393/05/15

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects off Rheum ribes L. syrup on bloody diarrhea in children aged 12 to 72 months.

Public title

Effects off Rheum ribes L. syrup on bloody diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : (1) age between 12 to 72 months; (2) history of passing loose stool (>3 times per day) mixed with blood and or mucus for ≤ 72 hours or >5 WBC in S/E, and (3) with or without the presence of fever, abdominal

pain, anorexia, dehydration, and vomiting; (4) written, voluntary informed consents from the parent or legal guardians of the children were obtained at the time of admission. Exclusion criteria:(1) refusal of consent by parents; (2) treatment with an antimicrobial and or antidiarrheal agents within last 3 days; (3) fecal presence of erythrophagocytic trophozoite of Entameba histolytica or cyst/trophozoites of Giardia lamblia; (4) presence of concurrent illnesses (pneumonia, sepsis, meningitis, and toxic colitis).

Age

From **12 months** old to **6 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **94**

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

Vice Chancellor for research,Yazd Shahid sadoughei univesity of medical sciences

Street address

central department of Shahid sadoughei medical university.Shahid bahonar squer.Yazd

City

Yazd

Postal code

8916978477

Approval date

2014-06-25, 1393/04/04

Ethics committee reference number

17/1/65410

Health conditions studied

1

Description of health condition studied

Bloody diarrhoea

ICD-10 code

A03

ICD-10 code description

Shigellosis

Primary outcomes

1

Description

Blood in stool

Timepoint

Before intervention and every 8 hours after intervention

Method of measurement

Direct inspection and asking patient`s parents

2

Description

Fever

Timepoint

At the beginning and then every 8 hours

Method of measurement

Thermometer

3

Description

Daily numbers of stools

Timepoint

Every 8 hours

Method of measurement

Asking from nurse of patient

4

Description

RBC in stool

Timepoint

In days 0, 3, 5

Method of measurement

Stool Exams

Secondary outcomes

empty

Intervention groups

1

Description

Ribes syrup children less than 15 KG 2,5 cc and more than 15 KG 5 cc every 6 hours fore 5 days

Category

Treatment - Drugs

2

Description

Placebo syrup(Basal ingredients of Ribes syrup with out Ribes) children less than 15 KG 2,5 cc and more than 15

KG 5 cc every 6 hours for 5 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ziaei hospital of Ardakan

Full name of responsible person

Ali khiveh

Street address

Azadi squar, Ziaei hospital

City

Ardakan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Shahid Sadougei University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Ezoddini

Street address

Central Building of Shahid Sadougei Medical University, Shahid Bahonar squer.Yazd

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research, Shahid Sadougei 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

Traditional Medicine Faculty of Ardakan, Shahid Sadougei University of Medical Sciences

Full name of responsible person

Ali Khiveh

Position

Ph.D candidate

Other areas of specialty/work

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Person responsible for updating data

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty