Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 to72 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-khiveh@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 to72 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 eyery 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 pationt

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 houres 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 houre 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 Sadoughei University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Ezoddini

Street address

Central Building of Shahid Sadoughei 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 Sadoughei 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 Sadoughei 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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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