

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of rhubarb (*Rheum ribes* L.) syrup in Children 1 to 6 years with acute diarrhea

Protocol summary

Study aim

Evaluating the effect of rhubarb syrup in children 1 to 6 years old with acute diarrhea

Design

Randomized clinical trial with two groups of rhubarb syrup and placebo that are entered in the study by permuted block randomization. Patients in both groups receive medication for 5 days and are followed for two weeks.

Settings and conduct

The study is performed in Referral Amirkala Babol Children's Hospital. Children hospitalized due to acute diarrhea, in addition to receiving the standard treatment in two groups in blind form, receive rhubarb syrup or placebo for 5 days. They are then followed up for up to two weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children 1 to 6 years with acute diarrhea (loose stools for more than 3 times a day) in the last 72 hours; stool white blood cell count less than 5 / HPF in stool with or without mucus; mild to moderate dehydration. Exclusion criteria: more than three days have passed since the onset of diarrhea; children treated with antibiotics or antidiarrheal drugs in the last 3 days; history of pneumonia, sepsis, meningitis, toxic colitis during diarrhea *Entamoeba histolytica* cyst; *Giardia lamblia* trophozoite in feces; dysentery (infectious and non-infectious); history of chronic diseases; immunodeficiency; other infections including urinary tract infections.

Intervention groups

Rhubarb syrup: this syrup is prepared using the aqueous extract of rhubarb *R. ribes* based on water and sugar 66.7% in the laboratory of medicinal plants of Shahid Beheshti University of Medical Sciences and is packaged in 120 ml amber jars with a label. The dose is 2.5 ml for children under 15 kg and 5 ml for children over 15 kg every 6 hours for 5 days. Placebo syrup: based on water and sugar in the amount of rhubarb syrup and with some

essential oil that gives the same smell. It is given in the same dose.

Main outcome variables

Time to recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200105046009N5**

Registration date: **2021-09-29, 1400/07/07**

Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**

Update count: **0**

Registration date

2021-09-29, 1400/07/07

Registrant information

Name

Seyyed Ali Mozaffarpur

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 4728

Email address

dr.mozaffarpur@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-01, 1400/07/09

Expected recruitment end date

2023-03-01, 1401/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of rhubarb (*Rheum ribes* L.) syrup in Children 1 to 6 years with acute diarrhea

Public title

The effect of rhubarb (*Rheum ribes* L.) syrup in Children with acute diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 1 to 6 years Acute diarrhea (loose stools for more than 3 times a day) in the last 72 hours Stool white blood cell count less than 5 / HPF in stool with or without mucus or blood Dehydration mild to moderate

Exclusion criteria:

More than three days have passed since the onset of diarrhea Children treated with antibiotics or antidiarrheal drugs in the last 3 days History of pneumonia, sepsis, meningitis, or toxic colitis during diarrhea *Entamoeba histolytica* cyst, *Giardia lamblia* trophozoite in stool exam Dysentery (infectious or non-infectious) Dry milk consumption Severe malnutrition (weight less than 60% or weight/height less than 70%) History of known chronic diseases Any type of food allergy Use of probiotics Immunodeficiency Other infections including urinary tract infections

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the random number table, children are divided into two groups: A, rhubarb syrup + standard treatment, and B, control group, which is standard treatment+ placebo syrup. Randomization will be performed using size 4 permutation blocks. In this method, an equal number of drugs (A) and placebo (B) will be placed in each block in random order. This will be done by a statistician.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the drug and placebo, it will be uniform in color, color and smell and will be prepared in exactly the same packaging and jars.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Babol University of Medical Sciences

Street address

Ganjafrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2021-08-31, 1400/06/09

Ethics committee reference number

IR.MUBABOL.REC.1400.185

Health conditions studied**1****Description of health condition studied**

Acute diarrhea

ICD-10 code

A08

ICD-10 code description

Viral and other specified intestinal infections

Primary outcomes**1****Description**

Time to recovery

Timepoint

Counting the days of diarrhea up to the normal defecation

Method of measurement

Recovery time from acute diarrhea is defined as the time interval between admission and cessation of diarrhea or the first normal bowel movements, which in the Bristol stool diagram is equivalent to a score below 5

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

Counting the day of hospitalization (the days from hospitalization up to the discharge)

Method of measurement

Counting the hospitalization days

Intervention groups

1

Description

Intervention group: Rhubarb syrup is prepared on the basis of USP 34 (USP simple syrup). USP simple syrup is based on water and sugar 66.7%. The syrup prepared is packaged in 120 ml amber jars with a label. The herbal medicine used in this design is a syrup made from the aqueous extract of *R. ribes* fruit. Preparation of *R. ribes* in the laboratory of medicines Herbal is performed by Shahid Beheshti School of Pharmacy in Tehran. The standard for total flavonoid content is 0.356 MG / ML in syrup. The total flavonoid on Rutin is also 7.13. The desired dose is 2.5 ml for children under 15 kg or 5 ml for children over 15 kg every 6 hours for 5 days.

Category

Treatment - Drugs

2

Description

Control group: placebo is made using a simple formula based on the USP standard of Pharmacoy Syrup, which includes a standard color, flavoring and appearance similar to rhubarb syrup. Finally, both products are placed in the same bottle and in the same packaging. will be provided.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkiola Pediatric Hospital

Full name of responsible person

Seyyedali Mozaffarpur

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Sarghord Ghasemi Street, Babol University of Medical Science, Babol, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Seyyed Ali Mozaffarpur

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Decide after the end of the study

When the data will become available and for how long

At the end of the study

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Decide after the end of the study

From where data/document is obtainable

email: seyyedali1357@gmail.com

What processes are involved for a request to access data/document

Ask via email: seyyedali1357@gmail.com

Comments