Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of rhubarb (Rheum ribes L.) syrup in Children 1to 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

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Iran (Islamic Republic of)

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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 1to 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
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Phone
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Email
Rezaghadimi@yahoo.com
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
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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)
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