Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of hydroalcoholic extract of Quercus brantii on acute watery diarrhea: A double-blind clinical trial

Protocol summary

Study aim

The effect of hydroalcoholic extract of Quercus brantii on acute watery diarrhea in children

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 0 on 80 patients.

Settings and conduct

This study is conducted on 80 children (6 months to 6 years old) with severe watery diarrhea who were hospitalized for 3 to 6 days in Imam Sajjad Yasouj Hospital. After completing the ethical form and being fully informed about participating in the research, the children's parents are randomly assigned to the control or intervention group based on the simple randomization method.

Participants/Inclusion and exclusion criteria

Children with acute watery diarrhea and moderate dehydration hospitalized in the children's department of Imam Sajjad Yasouj Hospital, Iran in 1401, registered informed consent from the parents of the children participating in the research.

Intervention groups

The control group of routine treatment and the intervention group of hydroalcoholic extract of Quercus brantii

Main outcome variables

1) Determining and comparing the average weight of the child on the first, second and third day in the intervention and placebo groups 2) Determining and comparing the average number of diarrhea on the first, second and third day in the intervention and placebo groups 3) Determine and compare the frequency of stool consistency (watery, soft and firm) on the first, second and third day in the intervention and placebo groups. 4) Determination and comparison of CBC, Diff, Na, K, BUN, Cr, BS, S/E, U/A in the intervention and placebo groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230105057060N1**
Registration date: **2023-05-06, 1402/02/16**
Registration timing: **retrospective**

Last update: **2023-05-06, 1402/02/16**
Update count: **0**

Registration date

2023-05-06, 1402/02/16

Registrant information

Name

Zeynab Daneshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3226 3835

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

2022-09-23, 1401/07/01

Actual recruitment end date

2023-02-20, 1401/12/01

Trial completion date

2023-02-20, 1401/12/01

Scientific title

The effect of hydroalcoholic extract of Quercus brantii on acute watery diarrhea: A double-blind clinical trial

Public title
The effect of hydroalcoholic extract of Quercus brantii on acute watery diarrhea in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 6-72 month Acute watery diarrhea in children Informed consent of the patient's parents
Exclusion criteria:
Chronic Diseases Severe malnutrition Bloody diarrhea Recent use of antibiotics Persistent vomiting Recent use of zinc supplements (last month) Drug intolerance
Age
From **6 months** old to **6 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
The technique of randomization is simple. The computer program "Computer Random Generation" will determine the assignment sequence. We will use sealed envelopes with codes to assign research units to the control and intervention groups (A, B).
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be conducted in a double-blind manner, so that the pharmacist will provide researchers with 80 bottles containing medicine (500 mg of oak extract) and placebo, which will have a code on each of them. The researcher and patients are not aware of its contents.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees
Street address
Jalil
City
Yasuj
Province
Kermanshah
Postal code
7591994779
Approval date
2022-05-18, 1401/02/28
Ethics committee reference number
IR.YUMS.REC.1401.011

Health conditions studied

1

Description of health condition studied
Diarrhea in children
ICD-10 code
R19.7
ICD-10 code description
Diarrhea, unspecified

Primary outcomes

1

Description
Children's weight
Timepoint
Hospitalization period
Method of measurement
Balance

2

Description
Frequency of diarrhea
Timepoint
The first and the last day of hospitalization
Method of measurement
Questionnaire

3

Description
Stool consistency
Timepoint
Examining stool consistency (watery, soft and hard) on the first, second and third day based on the daily stool consistency record form (Bristol scoring form)
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Blood and urine tests including CBC-Diff, Na, K, BUN, Cr,

BS, S/E, U/A

Timepoint

Before and after the study period

Method of measurement

Laboratory

Intervention groups

1

Description

The study is a randomized, a double-blind clinical trial including 80 children (6 to 6 years old) with severe watery diarrhea (no blood in stool and fewer than five white blood cells) for 3 to 6 days that were hospitalized in the hospital of Imam Sajjad Yasuj. The subjects are typically assigned to the control or intervention group using a simple random assignment method after completing an ethical form. The parents will being thoroughly informed about participating in the research. The study will begin after receiving the code of ethics from the university. Patients with watery diarrhea are admitted to Imam Sajjad Hospital in Yasuj city after taking a history and examining related tests, including blood and urine tests, including CBC-Diff, Na, K, BUN, Cr, BS, S/E. U/A are selected and randomly divided into two control and intervention groups, The study will be done in a double-blind manner. After preparing 80 bottles of simple syrup containing extract and placebo, the researcher and patient need to be made aware of the contents of the bottles because they are coded. The patient or the patient's companion is first given a questionnaire containing study variables such as fever, patient weight, and duration of hospitalization. The intervention group received 500 mg of oak extract orally in addition to the standard treatment for acute watery diarrhea (WHO protocol). In contrast, the control group received a placebo and the standard treatment for acute watery diarrhea (WHO protocol). The questionnaires are then filled out a second time with daily references for up to three days. After the collated questionnaires are made available to the statistician after the survey. In addition, supportive remedies, such as zinc and probiotics, are administered to aid in the regeneration of the villi.

Category

Treatment - Drugs

2

Description

Control group: placebo group:The same amount of placebo substance was used in containers that were completely similar to containers containing oak extract.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajjad Hospital in Yasuj

Full name of responsible person

Ali Keshtkari

Street address

Jalil

City

Yasouj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

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a_keshtkari@yahoo.com

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Ali Keshtkari

Street address

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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

Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Ali Keshtkari
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Zeynab Daneshi
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Resident
Latest degree
Medical doctor
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only a part of the data, such as the information related to the main outcome or the like, can be shared.
When the data will become available and for how long
2023
To whom data/document is available
Academic and scientific institutions
Under which criteria data/document could be used
Data validation
From where data/document is obtainable
Dr Zeynab Daneshi
What processes are involved for a request to access data/document
Contact the project manager
Comments