

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

dr.z.daneshi.med@gmail.com

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		Research Ethics Committees	
Public title	The effect of hydroalcoholic extract of Quercus brantii on acute watery diarrhea in children	Street address	
		Jalil	
Purpose	Treatment	City	
		Yasuj	
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	Province	
		Kermanshah	
Age	From 6 months old to 6 years old	Postal code	
		7591994779	
Gender	Both	Approval date	
		2022-05-18, 1401/02/28	
Phase	0	Ethics committee reference number	
		IR.YUMS.REC.1401.011	
Groups that have been masked		Health conditions studied	
- Participant - Care provider - Investigator		<u>1</u>	
Sample size		Description of health condition studied	
Target sample size: 80		Diarrhea in children	
Actual sample size reached: 70		ICD-10 code	
Randomization (investigator's opinion)		R19.7	
Randomized		ICD-10 code description	
Randomization description		Diarrhea, unspecified	
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).		Primary outcomes	
Blinding (investigator's opinion)		<u>1</u>	
Double blinded		Description	
Blinding description		Children's weight	
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.		Timepoint	
Placebo		Hospitalization period	
Used		Method of measurement	
Assignment		Balance	
Parallel		<u>2</u>	
Other design features		Description	
		Frequency of diarrhea	
Secondary Ids		Timepoint	
empty		The first and the last day of hospitalization	
Ethics committees		Method of measurement	
<u>1</u>		Questionnaire	
Ethics committee		<u>3</u>	
Name of ethics committee		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	
<u>1</u>		<u>1</u>	
Description		Description	
Blood and urine tests including CBC-Diff, Na, K, BUN, Cr,		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 be 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
Kohgiluyeh-va-Boyer-Ahmad
Postal code
7591994779
Phone
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Email
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Web page address
https://isid.research.ac.ir/Ali_Keshtkari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Ali Keshtkari
Street address
Jalil street
City
Yasouj
Province
Kohgiluyeh-va-Boyer-Ahmad
Postal code
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Email
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Web page 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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a_keshtkari@yahoo.com

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Person responsible for scientific 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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Web page address

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Person responsible for updating data

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Zeynab Daneshi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Yasuj

Province

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Postal code

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Phone

+98 74 3226 3835

Fax**Email**

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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