

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of N-acetylcysteine efficacy compared to placebo in the treatment of diarrhea caused by rotavirus in children: a randomized, double-blind clinical trial.

Protocol summary

Study aim

Determining the effectiveness of N-acetylcysteine in the treatment of diarrhea caused by rotavirus in children

Design

Control-controlled clinical trial with parallel, double-blind, randomized, phase 3 groups on 64 patients used the Excel software rand function for randomization.

Settings and conduct

This project was carried out at Shahid Sadoughi Hospital in Yazd. The patients in the drug group were given 60 mg/kg/day of N-acetylcysteine in three divided doses and placebo was given to the control group. In both groups, patients will receive supportive treatment such as ORS.

Participants/Inclusion and exclusion criteria

Children aged 6 months to 5 years with diarrhea caused by rotavirus, who do not have a specific underlying disease, do not have allergy to N-acetylcysteine, and do not take ibuprofen.

Intervention groups

In order to evaluate the effectiveness of N-acetylcysteine in the treatment of diarrhea caused by rotavirus, a group of 32 people is given N-acetylcysteine and a group of 32 people is given a placebo.

Main outcome variables

The number of days of the patient's diarrhea, the number of stools per day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041882N13**

Registration date: **2023-10-14, 1402/07/22**

Registration timing: **retrospective**

Last update: **2023-10-14, 1402/07/22**

Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

behrooz heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3820 8699

Email address

b.heydari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of N-acetylcysteine efficacy compared to placebo in the treatment of diarrhea caused by rotavirus in children: a randomized, double-blind clinical trial.

Public title

N-acetylcysteine in the treatment of diarrhea caused by rotavirus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Rotavirus infection has been confirmed in patient. The age range of the patient is between 6 months and 5 years
Absence of genetic or chronic diseases in patients
Insensitivity to N-acetylcysteine
Do not receive ibuprofen

Exclusion criteria:

Patients who refer after 48 hours from the onset of diarrhea. Patients who receive ibuprofen.
Hypersensitivity to N-acetylcysteine

Age

From **6 months** old to **5 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 64 patients were randomly divided into two treatment groups (A and B). In order to randomize, the block random allocation method was used, in which 13 blocks of 5 were considered. The letters A and B. These permutations were generated with the help of Random software distribution software version 1. For this purpose, the list prepared by software No. 1 to 64 is in 13 blocks of five in general to implement this I want the software output to the first eligible person number 1 and I want to select the last person number 64.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients, the physician, and the assessor of clinical symptoms will be all blinded to the intervention's assignments during performing the study. In this way, the first executor of the sequence plan determines the allocation of individuals according to the order in which patients enter the study and puts N-acetyl cysteine and placebo syrups (They are the same in terms of packaging) in the same shape boxes for patient consumption. And identifies them with codes A or B. The student then delivers the appropriate medications to the patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine- Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Science, Shohadaye Gomnam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2017-02-15, 1395/11/27

Ethics committee reference number

IR.SSU.MEDICINE.REC.1395.338

Health conditions studied

1

Description of health condition studied

Diarrhea caused by rotavirus

ICD-10 code

A08.0

ICD-10 code description

Rotaviral enteritis

Primary outcomes

1

Description

Investigation of duration and frequency of diarrhea

Timepoint

Days zero to seven

Method of measurement

Frequency of diarrhea per day and duration of diarrhea

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients aged 6 months to 5 years with diarrhea caused by rotavirus receive 60 mg/kg N-acetylcysteine syrup daily (prepared at Yazd Faculty of Pharmacy) in 3 divided doses orally until the end of the diarrhea period.

Category

Treatment - Drugs

2

Description

Control group: Patients aged 6 months to 5 years with diarrhea caused by rotavirus receive daily placebo syrup (prepared in Yazd Pharmacy Faculty) in 3 divided doses orally until the end of the diarrhea period.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid sadoughi hospital

Full name of responsible person

Majid Aflatunian

Street address

Ibn Sina Street, Shahid Ghandi Boulevard, Safaieh, Yazd.

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sadoghi-hospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

امین صالحی ابرقوئی

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Behrooz Heydari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

After nonrecognition, all data can be share

When the data will become available and for how long

6 months after publication

To whom data/document is available

All of researchers

Under which criteria data/document could be used

Nothing

From where data/document is obtainable

Behrooz Heydari email: b.heydari@ssu.ac.ir

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

Request your information by email. The data will be sent after a week.

Comments