Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy of Racecadotril in the Management of Acute Gastroenteritis in Children

Protocol summary

Study aim
To compare the effectiveness of racecadotril versus placebo in the management of acute gastroenteritis among children with some dehydration

Design
Open labeled, randomized controlled trial

Settings and conduct
Department of pediatrics, Rai Teaching Hospital, Sargodha, Pakistan.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Children of both genders, aged between 1 to 18 years, presenting with acute gastroenteritis with some dehydration. Exclusion Criteria: Children with malnutrition, osmotic diarrhea, chronic diarrhea, or bloody diarrhea. Immunocompromised children, and children having severe dehydration

Intervention groups
Children in Racecadotril group were given oral rececadotril in addition to the standard WHO treatment for acute gastroenteritis. Children in Placebo group were given only the standard WHO treatment along with 5 ml of distilled water in the form of a placebo for acute gastroenteritis. Both groups were given designated treatments for a duaration of 3 days.

Main outcome variables
Reduction in number of stools

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221231056999N4**
Registration date: **2024-05-16, 1403/02/27**
Registration timing: **prospective**

Last update: **2024-05-16, 1403/02/27**
Update count: **0**

Registration date
2024-05-16, 1403/02/27

Registrant information

Name
M Aamir

Name of organization / entity
RESnTEC, Institute of Research

Country
Pakistan

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+92 321 6801143

Email address
aamir@resntec.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-01, 1403/03/12

Expected recruitment end date
2024-09-01, 1403/06/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of Racecadotril in the Management of Acute Gastroenteritis in Children

Public title
Efficacy of Racecadotril in the Management of Acute Gastroenteritis in Children

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children of both genders Aged between 1 to 18 years

Presenting with acute gastroenteritis and some dehydration

Exclusion criteria:

Children with malnutrition Osmotic diarrhea Chronic diarrhea Bloody diarrhea Immunocompromised children Severe dehydration

Age

From **1 year** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done using envelop system. The envelopes were shuffled to ensure randomness. The envelopes were opened one by one, and each participant was allocated to either the Racecadotril group or the Placebo group. This process ensured that each participant had an equal chance of being assigned to either group, reducing the potential for bias in the assignment process. Children in Racecadotril group were given oral rececadotril in addition to the standard WHO treatment for acute gastroenteritis. Children in Placebo group were given only the standard WHO treatment along with 5 ml of distilled water in the form of a placebo for acute gastroenteritis.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Ethical and Research Committee, Rai Medical College & Teaching Hospital, Sargodha

Street address

6 Km Islamabad Road Sargodha

City

Sargodha

Postal code

4100

Approval date

2022-08-15, 1401/05/24

Ethics committee reference number

ERC/2022/093

Health conditions studied

1

Description of health condition studied

Acute Gastroenteritis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reduction in number of stools

Timepoint

3 days

Method of measurement

Parents or guardians of the studied children will be telephonically contacted and asked about the number of stools per day after 3 days of treatment.

Secondary outcomes

empty

Intervention groups

1

Description

racecadotril group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The department of pediatrics, Rai Teaching Hospital

Full name of responsible person

Dr. Sadaf Liaqat

Street address

6 Km Islamabad Road Sargodha

City

Sargodha

Postal code

40100

Phone

+92 306 6006806

Email

sadafliaqat09@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rai Medical College, Sargodha, Pakistan

Full name of responsible person
Dr. Sadaf Liaqat

Street address
6 Km Islamabad Road Sargodha.

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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
Rai Medical College, Sargodha, Pakistan

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
Department of Pediatric Medicine, Rai Medical College, Sargodha

Full name of responsible person
Dr. Sadaf Liaqat

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Not applicable

When the data will become available and for how long

6 months after publication

To whom data/document is available

All

Under which criteria data/document could be used

Contact corresponding author

From where data/document is obtainable

Contact corresponding author

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

Contact corresponding author

Comments