

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 racecadotril 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 duration 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

###### Phone

+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 racecadotril 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.

**City**

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**Postal code**

41100

**Phone**

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**Email**

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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

**Street address**

6 Km Islamabad Road Sargodha.

**City**

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**Province**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Department of Pediatric Medicine, Rai Medical College, Sargodha

**Full name of responsible person**

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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**