

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy and safety of enkefalinase inhibitor racecadotril in decreasing the duration and frequency of acute diarrhea in children 1 months to 5 years

Protocol summary

Summary

1)objectives: The present project aims to evaluate efficacy and safety of this drug in acute diarrhea in children under 5-years-old admitted in Mofid pediatric hospital. 2)Design: Not blinded randomized clinical trial in 1-months to 5-years children randomized into either intervention group with Racecadotril or control. There would be 50 cases in each group. 3)Setting and conduct: All eligible cases with the inclusion criteria randomized to intervention or control group. 4)Participants: Children 1-months to 5-years old with no special allergies, no liver or kidney diseases 5)Interventions: hydration therapy (as MANA and WHO protocol) and Racecadotril (1.5 mg per kg three doses a day for 5 days or up to diarrhea discontinues) 6)main outcome measures: duration and frequency of diarrhea and hospital stay days

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201607131264N8**
Registration date: **2017-05-12, 1396/02/22**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-12, 1396/02/22

Registrant information

Name

Sima Besharat

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 1224 4170

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of enkefalinase inhibitor racecadotril in decreasing the duration and frequency of acute diarrhea in children 1 months to 5 years

Public title

Efficacy and safety of racecadotril in treatment of acute diarrhea in children 1 months to 5-years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children 1 months to 5 years old; acute diarrhea Exclusion criteria: children younger than 1 months-old and older than 5 years-old; renal or hepatic failure; history of allergy to any medication

Age

From **1 month** old to **5 years** old

Gender

Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Sealed pockets will be used to randomize patients into cases and controls.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Unit of developing clinical research, Mofid hospital

City

Tehran

Postal code

Approval date

2016-05-21, 1395/03/01

Ethics committee reference number

IR.sbm.u.rec.1395.1

Health conditions studied

1

Description of health condition studied

acute diarrhea

ICD-10 code

A09.9

ICD-10 code description

Gastroenteritis and colitis of unspecified origin

Primary outcomes

1

Description

duration of diarrhea

Timepoint

days

Method of measurement

medical record

2

Description

frequency of diarrhea

Timepoint

daily

Method of measurement

numbers of defecation in 24 hours

Secondary outcomes

1

Description

duration of hospital stay

Timepoint

days

Method of measurement

medical record

Intervention groups

1

Description

Serum therapy (MANA protocol and WHO guidelines) and Racecadotril (1.5 mg per kg 3 doses in day for 5 days or when no diarrhea)

Category

Treatment - Drugs

2

Description

Only serum therapy

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Mofid Hospital

Full name of responsible person

Dr.Farid Imanzadeh

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Farid Imanzadeh

Street address

Mofid Hospital, Shariati ave., Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Farid Imanzadeh

Position

Pediatric gastroentrologist

Other areas of specialty/work

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Contact

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Mahsa Besharat

Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty