Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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.sbmu.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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Person responsible for updating data

Contact

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Full name of responsible person

Mahsa Besharat

Position

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Other areas of specialty/work

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Web page address

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