

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The comparison of oral calcium effect in addition to conventional treatment in duration of diarrhea with convention treatment alone in children admitted due to acute gastroenteritis

Protocol summary

Summary

(1) Objectives: The evaluation oral calcium effect in addition to conventional treatment in duration of diarrhea in children admitted in hospital due to acute gastroenteritis. (2) Design: In this single blind randomized clinical trial we have studied patients one month to 12 years old with acute and noninflammatory diarrhea who had needed to admit in hospital for receiving intravenous therapy (inclusion criteria). The patients who had inflammatory diarrhea; chronic or secondary diarrhea; and those who primarily had serum calcium out of normal level, were excluded from our study (exclusion criteria). Finally, 124 patients divided randomly to two groups of 62. The control group received conventional treatment including serum therapy and correcting electrolytic and acid base derangements. The intervention group received calcium complement as calcium gluconate 10% , 0.5cc/kg in 3 divided dose per day as open label administration in addition to conventional therapy. The duration, times and volume of diarrhea (primary outcome), and adverse effects appeared during treatment (secondary outcome), and other variables were compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110624900N1**
Registration date: **2017-01-25, 1395/11/06**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-25, 1395/11/06

Registrant information

Name

Mojgan Amrolalaie

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 2041

Email address

sayyahfar.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of oral calcium effect in addition to conventional treatment in duration of diarrhea with convention treatment alone in children admitted due to acute gastroenteritis

Public title

Evaluation of calcium effect in Children Gastroenteritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients one month to 12 years of age

with acute and noninflammatory diarrhea who had needed to admit in hospital for receiving intravenous therapy
Exclusion Criteria: The patients who had chronic diarrhea; or secondary diarrhea(due to sepsis , uti, drugs, endocrine or metabolic); those who primarily had serum calcium out of normal level; and those who gave up contribution, excluded from our study

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **124**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Iran University of Medical Science

Street address

Hemmat Highway

City

Tehran

Postal code**Approval date**

2014-05-26, 1393/03/05

Ethics committee reference number

1790

Health conditions studied**1****Description of health condition studied**

Acute Gastroenteritis

ICD-10 code

A09.0

ICD-10 code description

other and unspecified gastroenteritis and colitis of infectious origin

Primary outcomes**1****Description**

duration, intensity and volume of diarrhea

Timepoint

days of 1, 3, 7 after treatment

Method of measurement

duration of diarrhea, times, and volume of stool (mother assesment)

Secondary outcomes**1****Description**

Adverse effects of treatment including nausea, vomiting, abdominal pain, constipation

Timepoint

days of 1, 3 ,7 after treatment

Method of measurement

patient visit, question from nurse or mother

Intervention groups**1****Description**

Intervention group: Administration of gluconate calcium 10%, 0.5 ml/kg/day in 3 divided doses for 3 days in addition to conventional treatment including rehydration, correcting electerlites and acid base derangements

Category

Treatment - Drugs

2**Description**

Control group: Conventional therapy including rehydration, correcting electerolites and acid and base derangements

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Hazrat Aliasghar Children Hospital

Full name of responsible person

Dr Mojgan Amrolalaie

Street address

Zafar Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Science/Hazrat Aliasghar Hospital

Full name of responsible person

Dr Mojgan Amrolalaie

Street address

Zafar Street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Science/Hazrat Aliasghar Hospital

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

Iran University of Medical Science

Full name of responsible person

Dr Mojgan Amrolalaie

Position

Pediatric Subspeciality Resident

Other areas of specialty/work

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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