

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of response to standard treatment plus therapeutic vitamin D dose, with standard treatment and maintenance vitamin D in children with functional constipation, randomized clinical trial

Protocol summary

Study aim

The aim of this study is evaluation of supplemental vitamin D effect in management of functional constipation in children. Patients suffer from functional constipation and low serum level of vitamin D randomized to receive standard treatment protocol of constipation with or without vitamin D. Their therapeutic response will be evaluate and compare in 4, 8 weeks and 3 months in both groups.

Design

The patients will be randomized with block method to 1- standard regimen for constipation therapy 2- standard regimen plus vitamin D therapy

Settings and conduct

patients are selected from clients to Valiasr hospital with complaint of constipation without any red flag aged 1-18 years and vitamin D deficiency. They are randomized to two intervention (constipation therapy and therapeutic dose of vitamin D) and control (constipation therapy and maintenance dose of vitamin D) groups. Their response to treatment are assessed and compared at 4 and 8 weeks and third months.

Participants/Inclusion and exclusion criteria

Any patient aged 1-18 years old with functional constipation and vitamin D deficiency is included and any patient with red flags such as low age, FTT, abnormal physical exam, history of abdominal surgery is excluded

Intervention groups

The standard therapeutic protocol vs standard with therapeutic dose of vitamin D

Main outcome variables

Therapeutic response is evaluated based on fecal frequency and consistency, fecal incontinence ,abdominal pain and difficulty in defecation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121107011392N3**

Registration date: **2020-10-20, 1399/07/29**

Registration timing: **prospective**

Last update: **2020-10-20, 1399/07/29**

Update count: **0**

Registration date

2020-10-20, 1399/07/29

Registrant information

Name

Masoumeh Asgarshirazi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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m_shirazi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of response to standard treatment plus therapeutic vitamin D dose, with standard treatment and maintenance vitamin D in children with functional constipation, randomized clinical trial

Public title

Comparison of response to standard treatment plus therapeutic vitamin D dose, with standard treatment and maintenance vitamin D in children with functional constipation, randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Any patient with functional constipation aged 1-18 years old

Exclusion criteria:

Any red flag such as patient's age less than 1 yr, FTT, abdominal distention, enterocolitis history or any abnormal finding in examination, history of constipation therapy in last 4 wks, mental retardation, hypothyroidism, celiac disease, cystic fibrosis or hx of abdominal surgery .

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study constipated patients with vitamin D deficiency have been divided in two intervention and control groups based on block randomization based on intervention and control groups(A,B) two allele block no 4:AA BB/AB AB/ BA BA/BB AA/BA AB/AB BA

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients and their parents don't know the role of supplemental vit D in constipation treatment

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of children medical center, Tehran University of Medical Sciences

Street address

Gharib Ave., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2020-08-27, 1399/06/06

Ethics committee reference number

IR.TUMS.CHMC.REC.1399.106

Health conditions studied

1

Description of health condition studied

functional constipation

ICD-10 code

K59.0

ICD-10 code description

K59.0

2

Description of health condition studied

Functional constipation based on ROME IV criteria

ICD-10 code

K59.0

ICD-10 code description

K59.0

Primary outcomes

1

Description

Therapeutic response

Timepoint

4 and 8 weeks and 3 months after therapy

Method of measurement

Check list for fecal frequency and consistency

Secondary outcomes

1

Description

Complication as abdominal pain, nausea and vomiting and fecal incontinence

Timepoint

4 and 8 weeks and 3 months after therapy

Method of measurement

Check list and question

Intervention groups

1

Description

Those that receive standard constipation treatment plus therapeutic dose of vitamin D

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Pediatrics clinic of Valiasr Hospital

Full name of responsible person

Masoumeh Asgarshirazi and Mojtaba Fazel

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Valiasr Hospital. Imam Khomeini Hospital Complex .
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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhoundzade

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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

Tehran University of Medical Sciences

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**

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Asgarshirazi

Position

Associate professor of pediatric gastroenterology

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

Associate professor of pediatric gastroenterology

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

First through proposal and last through main report to
Tehran University of Medical Sciences

When the data will become available and for how long

20 months

To whom data/document is available

professionals in pediatrics

Under which criteria data/document could be used

Evaluation and continue

From where data/document is obtainable

Executor in charge: Mojtaba Fazel MD

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

contact through Email

Comments