

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of treatment of attention deficit hyperactivity disorder (ADHD) with and without routine treatment of constipation on improvement of clinical symptoms in patients with functional constipation: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of treatment of attention deficit hyperactivity disorder (ADHD) with and without routine treatment of constipation on improvement of clinical symptoms in patients with functional constipation

Design

This a randomized clinical trial, phase II, in which 80 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with attention deficit hyperactivity disorder who will refer to Besat Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 4 to 12 years Attention deficit hyperactivity disorder for at least 6 months Functional constipation Exclusion criteria: Oppositional depressive disorder Learning disorder

Intervention groups

Intervention group: Treatment of attention deficit hyperactivity disorder including Ritalin 0.3 to 1 mg/kg 3 times per day for 3 to 5 days Control group: Treatment of attention deficit hyperactivity disorder including Ritalin 0.3 to 1 mg/kg 3 times per day for 3 to 5 days plus routine treatment constipation including powder Pidrrolax 0.7 mg/kg twice a day for 3 to 5 days

Main outcome variables

Primary outcome: Assessing the constipation before intervention and one week after that thought history taking

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N222**

Registration date: **2018-05-26, 1397/03/05**

Registration timing: **retrospective**

Last update: **2018-05-26, 1397/03/05**

Update count: **0**

Registration date

2018-05-26, 1397/03/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

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poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of treatment of attention deficit hyperactivity disorder (ADHD) with and without routine treatment of constipation on improvement of clinical symptoms in patients with functional constipation: a randomized clinical trial

Public title
Effect of treatment of attention deficit hyperactivity disorder (ADHD) with and without routine treatment of constipation on improvement of clinical symptoms in patients with functional constipation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 4 to 12 years Attention deficit hyperactivity disorder for at least 6 months Functional constipation
Exclusion criteria:
Oppositional depressive disorder Learning disorder

Age
From **4 years** old to **12 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups through drawing of lots

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province

Hamadan
Postal code
6517838695
Approval date
2017-02-18, 1395/11/30
Ethics committee reference number
IR.UMSHA.REC.1395.535

Health conditions studied

1

Description of health condition studied

Functional constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

Primary outcomes

1

Description

Assessing the constipation

Timepoint

before intervention and one week after that

Method of measurement

Thought history taking

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment of attention deficit hyperactivity disorder including Ritalin 0.3 to 1 mg/kg 3 times per day for 3 to 5 days

Category

Treatment - Drugs

2

Description

Control group: Treatment of attention deficit hyperactivity disorder including Ritalin 0.3 to 1 mg/kg 3 times per day for 3 to 5 days plus routine treatment constipation including powder Pidrolax 0.7 mg/kg twice a day for 3 to 5 days or Bisacodyl 5 mg per day for 3 to 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Alireza Momeni

Street address

Besat Hospital, Shahed Square

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6517838695

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Alireza Momeni

Position

Resident of Pediatric

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact**Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available