Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Risperidone and placebo in the treatment of fecal incontinence in children 4 -18 years of age suffering from functional constipation and fecal incontinence, with and without neuropsychiatric disorders

Protocol summary

Study aim

Evaluating the effect of Risperidone on the treatment of fecal incontinence in functional constipation in children 4 to 18 years old with neurodevelopmental disorders and children without neuropsychiatric disorders

Design

Random allocation by stratified randomization and using the permuted block randomization method with quadruple and binary blocks was performed. Based on the sample size of 136 subjects, the blocks of size 2 and 4 were produced using the online site (www.sealedenvelope.com). The clinical trial has a control group, with parallel group design and it was double-blind, randomized, phase 3.

Settings and conduct

The study site of pediatric gastrointestinal and psychiatric clinics of Mofid and Loghman hospitals in Tehran, Iran. Blinding: double-blind. In the evaluation phase, researchers could not differentiate intervention from the control group until the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Functional constipation; Fecal incontinence; Age between 4 to 18 years old Exclusion criteria: Anatomical or hormonal causes for constipation; Presence of other GI disorders

Intervention groups

Intervention group: receiving Risperidone. The participants received a dose of 0.25-0.5 mg every 12 hours of Risperidone syrup daily for 12 weeks. Control group: receiving placebo. The participants received a dose of 0.25-0.5 mg every 12 hours of placebo syrup daily for 12 weeks.

Main outcome variables

Fecal incontinence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200203046352N1**
Registration date: **2022-06-19, 1401/03/29**
Registration timing: **retrospective**

Last update: **2022-06-19, 1401/03/29**
Update count: **0**

Registration date

2022-06-19, 1401/03/29

Registrant information

Name

Seyedehleila Tabatabaeifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7021

Email address

leilatabatabaee@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-01, 1398/10/11

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

2019-12-22, 1398/10/01

Actual recruitment end date

2021-02-19, 1399/12/01

Trial completion date

2021-06-20, 1400/03/30

Scientific title

Comparison of the effect of Risperidone and placebo in the treatment of fecal incontinence in children 4 -18 years of age suffering from functional constipation and fecal incontinence, with and without neuropsychiatric disorders

Public title

Impact of Risperidone in the treatment of fecal incontinence among children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Functional constipation Fecal incontinence Age between 4 and 18 neuropsychiatric disorders in half of participants Absence of neuropsychiatric disorders in half of participants

Exclusion criteria:

Anatomical and hormonal causes of constipation Presence of other GI disorders

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **140**

Actual sample size reached: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

Considering that BMI Z-score and psychological disorder can have a great impact on the results of the study, to ensure the uniform distribution of these variables in the groups, random allocation by Stratified Randomization and using the Permuted block randomization method with quadruple and binary blocks were used. Based on the sample size of 136 subjects, the quadruple block or double block were produced using the online site (www.sealedenvelope.com). Due to the double-blindness of the study, before starting the study, sets of packages containing Risperidone were prepared by someone other than the researcher, and the placebo was similar in appearance to Risperidone syrup. Indeed, researchers in the evaluation phase, from the allocation of participants in each of the groups (intervention and control group) until the end of the intervention, were not know the groups whereby the patients were randomized. In order to apply concealment in the randomization process, unique codes were used on the medicine boxes, and the desired code is also generated by the software. With this method of concealment, none of the participants and researchers know which of the two groups received the Risperidone or placebo. These codes were inserted on the packages by the company receiving the supplements and placebos. Upon each person entering the study, based on the sequence generated, the drug package in which the code is recorded was assigned to the parents. Also, the random sequence generated during the study was unpredictable.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medicine and placebo look exactly the same(shape, size, colour, smell). None of the participants are informed of receiving a placebo. Other than the manufacturer, nobody can differentiate medicine from a placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Pajoohan Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Koodakyaar dead end alley, Daaneshjoo Blvd, Chamraan highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-01-04, 1398/10/14

Ethics committee reference number

IR.SBMU.MSP.REC.1398.833

Health conditions studied

1

Description of health condition studied

Functional constipation, Fecal incontinence, NDD

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
fecal incontinence
Timepoint
every month for 6 months
Method of measurement
interview with parents

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 34 patients with functional constipation and fecal incontinence who receive a daily dose of 0.25-0.5 mg (every 12 hours) of risperidone syrup for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: 34 patients with functional constipation and fecal incontinence who receive a daily dose of 0.25-0.5 mg (every 12 hours) of placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatrics GI and psychiatry clinic,Mofid Children Hospital, Pediatrics GI clinic; Loghman Hospital
Full name of responsible person
Dr. Ghazaal Zahed
Street address
Mofid Chidren's Hospital, Shariati St., Tehran
City
Tehran
Province
Tehran
Postal code
1546815514
Phone
+98 21 2222 7021
Fax
+98 21 2222 0254
Email
ghazal.zahed@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ghazaal Zaahed
Street address
Shahid Arabi ave., Daneshjoo Blvd.,Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Fax
Email
info@sbmu.ac.ir
Web page address
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
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Ghazaal Zaahed
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address
Mofid Chidren's Hospital, Shariati street, Tehran
City
Tehran
Province
Tehran
Postal code
1546815514
Phone

+98 21 2222 7021

Email

ghazal.zahed@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Ghazaal Zaahed

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Mofid Chidren's Hospital, Shariati street, Tehran

City

Tehran

Province

Tehran

Postal code

1546815524

Phone

+98 21 2222 7021

Email

ghazal.zahed@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Ghazaal Zaahed

Position

Assistant professor

Latest degree

Subspecialist

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Psychiatrics

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Mofid Chidren's Hospital, Shariati street, Tehran

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ghazal.zahed@gmail.com

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

We would like to share every document that will be resulted in this research by considering our patients personal information that are secret. Demographic data,signs and symptoms anf effect of our treatment

When the data will become available and for how long

After finalizing the research and evaluation the results and for unlimited time

To whom data/document is available

Gastroenterologist (adults and pediatrics) pediatricians, pediatric and general surgeons

Under which criteria data/document could be used

By considering patients information as secret file

From where data/document is obtainable

Pediatric gastroenterology,hepatology and nutrition research center ,Shahid Beheshti University of Medical Sciences,Tehran,Iran

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

By formal e-mail

Comments

none