

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Effect of constipation treatment versus control group on migraine headaches in children with concurrent functional constipation: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of constipation treatment versus control group on migraine headaches in children with concurrent functional constipation

Design

This is a randomized clinical trial, phase II, in which 100 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible children with migraine headaches and concurrent functional constipation referring to the Besat Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 4 to 15 years, Migraine headaches with concurrent functional constipation,
Exclusion criteria: Contraindication of propranolol (asthma, liver disease, diabetes, bradycardia, heart block), Severe hypotension

Intervention groups

Intervention group: Intravenous infusion of propranolol 1 mg/kg up to 80 mg/day plus oral powder Pidrrolax without electrolyte 0.7 g/kg twice daily and also Bisacodyl suppository 5 mg daily for 3 to 5 days
Control group: Intravenous infusion of propranolol 1 mg/kg up to 80 mg/day

Main outcome variables

Primary outcome: Rectal impaction with digital rectal exam daily for 5 days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N361**

Registration date: **2020-07-26, 1399/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-26, 1399/05/05**

Update count: **0**

Registration date

2020-07-26, 1399/05/05

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

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of constipation treatment versus control group on

migraine headaches in children with concurrent functional constipation: a randomized clinical trial

Public title
Effect of constipation treatment versus control group on migraine headaches in children with concurrent functional constipation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 4 to 15 years, Migraine headaches with concurrent functional constipation,
Exclusion criteria:
Contraindication of propranolol (asthma, liver disease, diabetes, bradycardia, heart block), Severe hypotension

Age
From **4 years** old to **15 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

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
2020-01-25, 1398/11/05
Ethics committee reference number
IR.UMSHA.REC.1398.951

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Rectal impaction
Timepoint
Daily for 5 days
Method of measurement
With digital rectal exam

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intravenous infusion of propranolol 1 mg/kg up to 80 mg/day plus oral powder Pidrrolax without electrolyte 0.7 g/kg twice daily and also Bisacodyl suppository 5 mg daily for 3 to 5 days
Category
Treatment - Drugs

2

Description
Control group: Intravenous infusion of propranolol 1 mg/kg up to 80 mg/day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Besat Hospital in Hamadan city
Full name of responsible person
Maryam Shirmohamadi
Street address
Besat Hospital, Shahed Square
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3364 0030
Email
mshirmoo@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir

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

Maryam Shirmohamadi

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

mshirmoo@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Hasan Bazmamoon

Position

Podiatrist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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hbazmamoun@yahoo.com

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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School of Public Health, Hamadan University of
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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