Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A comparative study of the effect of bethanechol and domperidone on food tolerance in children with food intolerance

Protocol summary

Study aim
Comparative effect of bethanechol and domperidone in patients with feeding intolerance

Design
A parallel-group, triple-blind, randomized, phase 2 clinical trial on 214 patients. www.randomization.com was used for randomization.

Settings and conduct
In this study patients suffering from oral feeding intolerance who will be admitted to the pediatric special care department of Mashhad Akbar Hospital. The study will be triple blind in which the statistical consultant of the project who are the data analysts, the patients and the outcome evaluators are blind. Since the patients are children, they have been classified into intervention groups after obtaining informed consent from their parents. The outcome evaluator records the patient's clinical information and does not have information about the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: One month to 18 years of hospitalization in the pediatric intensive care unit؛ Patients with nutritional intolerance. Non-inclusion criteria: the cause of intolerance is one of the remediable causes such as electrolyte disorder, constipation, or ileus.

Intervention groups
Intervention group 1: Demperidone in children with a dose of 0.25 to 0.5 mg of base per kilogram of weight orally 3 or 4 times a day. Intervention group 2: Betancol in children orally 0.5 mg per kilogram of body weight per day in 3 divided doses with a maximum dose of 10 mg per dose and 1 hour before meals or 2 hours after meals.

Main outcome variables
Nutritional tolerance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190522043672N5**
Registration date: **2023-05-17, 1402/02/27**
Registration timing: **prospective**

Last update: **2023-05-17, 1402/02/27**
Update count: **0**

Registration date
2023-05-17, 1402/02/27

Registrant information

Name
Majid Sezavar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3870 9225
Email address
sezavardm@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of bethanechol and domperidone on food tolerance in children with food intolerance

Public title
The effect of bethanechol and domperidone on oral feeding intolerance
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
One month to 18 year children, hospitalized in the pediatric intensive care unit Patients with nutritional intolerance
Exclusion criteria:
The cause of intolerance is one of the remediable causes such as electrolyte disorder, constipation or ileus
Age
From **1 month** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **214**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization sequence generation will be done using www.randomization.com. Codes A and B are considered for patients, and allocation concealment will be done using opaque sealed envelopes.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The statistical consultant, the data analyst, the patients, and the outcome assessor are blinded. As the patients are children, they have no knowledge and information about the type of intervention. After obtaining informed consent from their parents, they have been classified into intervention groups. The evaluator who records the patient's clinical outcomes has no information about the type of intervention. Because the intervention is given by a nurse or doctor, the person registering does not know about the type of intervention. For the statistical consultant, the type of intervention is coded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9195965919
Approval date
2023-02-14, 1401/11/25
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.012

Health conditions studied

1

Description of health condition studied
Malabsorption due to intolerance
ICD-10 code
K90.4
ICD-10 code description
Malabsorption due to intolerance, not elsewhere classified

Primary outcomes

1

Description
Nutritional tolerance
Timepoint
Daily review from the first day of intervention
Method of measurement
Specialist clinical examinations

Secondary outcomes

1

Description
Possible side effects during hospitalization
Timepoint
Daily examination during hospitalization
Method of measurement
Clinical examination by experts

Intervention groups

1

Description
Intervention group1: Domperidone in children 0.25 to 0.5 mg/kg, orally 3 or 4 times a day

Category
Treatment - Drugs

2

Description
Intervention group 2: Children receive bethanechol orally at 0.5 mg/ kg/ day in 3 divided doses with a maximum dose of 10 mg per dose. It is taken 1 hour before or 2 hours after food.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Children's Hospital
Full name of responsible person
Majid Sezavar
Street address
Akbar Children's Hospital, in front of Shahid Kaveh 14, Shahid Kaveh Boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
9173595100
Phone
+98 51 3870 9225
Email
iomresearch@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Majid Ghayor Mobarhan
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
1394491388
Phone
+98 51 3841 1538
Email
GhayourM@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Majid Sezavar
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Akbar Children's Hospital, in front of Shahid Kaveh 14, Shahid Kaveh Boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
9173595100
Phone
+98 51 3870 9225
Email
sezavardm@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Sezavar
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Phone
+98 51 3870 9225
Email
sezavardm@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Sezavar
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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City
Mashhad
Province
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Phone
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Email
sezavardm@mums.ac.ir

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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The main and secondary outcome can be shared.
When the data will become available and for how long
Six months after the results are published
To whom data/document is available
Researchers affiliated with academic centers
Under which criteria data/document could be used
For the use of researchers affiliated with academic centers for scientific studies
From where data/document is obtainable
Dr.Majid Sezavar
What processes are involved for a request to access data/document
Request via email to sezavardm@mums.ac.ir
Comments