

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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: Domperidone 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**

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 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

**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

**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**