Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of Vitamin B6 (pyridoxine) Effect on symptoms and quality of life in patients with irritable bowel syndrome (IBS)

Protocol summary

Study aim
Evaluation of Vitamin B6 (pyridoxine) Effect on symptoms and quality of life in patients with irritable bowel syndrome (IBS) based on the Rome IV criteria.

Design
A randomized, double-blind, parallel-group clinical trial with a placebo-controlled study will be conducted on 60 patients for a duration of 4 weeks.

Settings and conduct
The study takes place at a private clinic in Mashhad city. After obtaining informed consent and checking entry and exit criteria, patients are assigned to treatment group A or B by concealed envelope method. Each patient will complete the IBSSS and IBS-QOL questionnaires. The patient is provided with the assigned medication code, and they receive a bottle of medication from category A or B from the pre-determined pharmacy. After 28 days, patients will be re-evaluated using the IBSSS and IBS-QOL. Until the data collection is complete, only the pharmacist is aware of the content of drug A and B.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Newly diagnosed patients with Irritable Bowel Syndrome (IBS) according to the Rome IV criteria; Age from 18 to 65 years Exclusion criteria: Personal History of malignant diseases of the gastrointestinal tract; Celiac disease; Lactose intolerance; Diverticulitis; Gastrointestinal infection; Hypothyroidism and hyperthyroidism; Presence of other diseases during colonoscopy in individuals over 50 years of age; Pregnancy and lactation; Allergy to the study drug; Lack of consent to participate in the study

Intervention groups
Intervention group: Vitamin B6 (pyridoxine) tablet, 40 mg, every 12 hours for a duration of four weeks Control group: Placebo tablet, 40 mg, every 12 hours for a duration of four weeks

Main outcome variables
Abdominal pain intensity, abdominal distension severity, satisfaction level with bowel movements, and quality of life of patients before and after intervention by using questionnaires.

General information

Reason for update
Completion of patient enrollment in the study

Acronym
PIBS

IRCT registration information
IRCT registration number: **IRCT20211226053534N2**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **prospective**

Last update: **2025-01-07, 1403/10/18**
Update count: **1**

Registration date
2023-08-12, 1402/05/21

Registrant information

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Elham Mokhtari Amirmajdi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-06, 1402/06/15

Expected recruitment end date
2024-05-04, 1403/02/15

Actual recruitment start date
2023-10-01, 1402/07/09

Actual recruitment end date
2024-12-22, 1403/10/02
Trial completion date
2024-12-22, 1403/10/02

Scientific title
Evaluation of Vitamin B6 (pyridoxine) Effect on symptoms and quality of life in patients with irritable bowel syndrome (IBS)

Public title
Evaluation of Vitamin B6 (pyridoxine) Effect on symptoms and quality of life in patients with irritable bowel syndrome (IBS)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Newly diagnosed patients with Irritable Bowel Syndrome (IBS) according to the Rome IV criteria Age from 18 to 65 years old
Exclusion criteria:
Personal History of malignant diseases of the gastrointestinal tract, Celiac disease, Lactose intolerance, Diverticulitis, Gastrointestinal infection, Hypothyroidism and hyperthyroidism Presence of other diseases during colonoscopy in individuals over 50 years of age Pregnancy and lactation Allergy to the study drug Lack of consent to participate in the study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on the two study arms and three categories of IBS (predominant constipation, diarrhea, or mixed) diagnosed using the Rome IV criteria, a randomization list is created using an online randomization software in blocks of six. Through this method, a unique code is generated for each individual. Each code, along with the medication category A or B, is placed in a sealed envelope. Upon the individual's entry into the study and in the order specified by the randomization list, the envelope is opened by the diagnosing physician, and the patient is randomly assigned to either the treatment group receiving drug A or drug B. Both the physician and the patient are blinded to the content of drugs A and B. The patient is provided with the assigned medication code, and they receive a bottle of medication from category A or B from the pre-determined pharmacy, which holds these bottles.
Blinding (investigator's opinion)
Double blinded
Blinding description
Until the end of data collection, only the pharmacist will be aware of the content of drugs A and B, and until that time, all participants and researchers will remain blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Mashhad Medical Science Islamic Azad University
Street address
Dr. Shahinfar Medical Faculty; Islamic Azad University Of Mashhad, Imam Khomeini 14, Imam Khomeini St
City
Mashhad
Province
Razavi Khorasan
Postal code
9187147578
Approval date
2023-07-19, 1402/04/28
Ethics committee reference number
IR.IAU.MSHD.REC.1402.043

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome
ICD-10 code
K58
ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Irritable bowel syndrome severity
Timepoint
At beginning of the study and four weeks after initiation of the study
Method of measurement
The irritable bowel severity scoring system (IBSSS)

Secondary outcomes

1

Description
Quality of life in patients with irritable bowel syndrome
Timepoint
At beginning of the study and four weeks after initiation of the study
Method of measurement
Irritable bowel syndrome quality of life questionnaire (IBS-QOL)

Intervention groups

1

Description
Intervention group: Vitamin B6 (pyridoxine) tablet, 40 mg, every 12 hours for a duration of four weeks.
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet, 40 mg, every 12 hours for a duration of four weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Mokhtari clinic
Full name of responsible person
Dr. Elham Mokhtari Amir Majdi
Street address
No. 11, Sajjad Boulevard, between Khayam boulevard and Golriz Street
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
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Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The non-identifiable statistical data of the participants will be shared collaboratively.

When the data will become available and for how long
Access will be provided upon publication of the relevant study articles.

To whom data/document is available
Researchers at scientific institutions.

Under which criteria data/document could be used
Studies in the field of irritable bowel syndrome.

From where data/document is obtainable
To receive the documents via email, please send your request and the reason for it to person responsible for general inquiries of the study. After reviewing it in the shortest possible time, a response to your request will be sent. Email address: dpusaz@gmail.com

What processes are involved for a request to access data/document
Through email. dousaz@gmail.com

Comments