Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effect of vitamin B1,B6,B12 and magnesium in disease activity, quality of life and chronic fatigue of inflammatory bowel disease

Protocol summary

Study aim
Comparison of the average scores of the disease activity/quality of life/fatigue questionnaire between 2 groups receiving 1, B6, B12B and magnesium supplements and placebo between the two groups and within each group at the beginning and end.

Design
The intervention will be done in a randomized block method and double-blind on 98 patients

Settings and conduct
The study is conducted in a double-blind way in a specialized clinic for digestive and liver diseases.The duration of the intervention is 4 weeks in the form of Neurobion and magnesium supplementation or placebo. The dosage of the supplement includes 100 mg of vitamin B1, 100 mg of vitamin B6, 200 micrograms of vitamin B12 and 250 mg of magnesium supplement daily. At the beginning of the study, people with IBD disease will be included in the study based on the doctor's definitive diagnosis and based on the mentioned entry criteria and answers to the mentioned questionnaires and filling the informed consent form.

Participants/Inclusion and exclusion criteria
The age of patients should be between 18-65 years Patients with inflammatory bowel disease. Body mass index in the normal range (18-24.9) Not suffering from other chronic inflammatory and autoimmune diseases Absence of pregnancy or breastfeeding, being an athlete or being hospitalized Lack of severe mental and behavioral disorders Not using nicotine and its derivatives in the last 6 months No chronic use of antibiotics, corticosteroids, and immunosuppressants ؛exclusion criteria: Suffering from other inflammatory diseases Use of thiopurines Taking contraceptives and antidepressants

Intervention groups
in the intervention group, one tablet of Neurobion and one tablet of magnesium will be taken daily, and in the placebo group, two placebo tablets will be taken daily for 28 days.

Main outcome variables
Disease activity؛quality of life ؛ chronic fatigue؛muscle strength

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090822002365N28**
Registration date: **2023-04-29, 1402/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-29, 1402/02/09**
Update count: **0**

Registration date
2023-04-29, 1402/02/09

Registrant information

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Mohammad Reza Vafa

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin B1,B6,B12 and magnesium in disease activity, quality of life and chronic fatigue of inflammatory bowel disease

Public title

Vitamins and Mg in IBD

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

IBD patients in remission Absence of anemia Body mass index in the normal range (18-24.9) - Not suffering from other chronic inflammatory and autoimmune diseases Absence of pregnancy or breastfeeding, and not being an athlete or being hospitalized - Absence of severe mental and behavioral disorders Not using nicotine and its derivatives in the last 6 months No chronic use of antibiotics, corticosteroids and immunosuppressants Not taking vitamin and mineral supplements in the last month Monthly consumption of one vitamin D pearl of 50,000 units

Exclusion criteria:

Suffering from reflux and stomach ulcer and receiving antacid drugs. Suffering from other inflammatory diseases Use of thiopurines Taking contraceptives and antidepressants

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

the participants in this study are divided into placebo and supplement groups based on random codes after completing the consent form. The way of assigning a random number to placebo or supplement is based on milk or line, then the numbers are also printed on the pill boxes during the presence of the patients. In the doctor's office, an envelope containing a number of random numbers is removed, and the number inside the envelope is the patient's number and the number of the can he received.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients participating in the project and the researcher are unaware that each of the patients will receive a placebo or a supplement. And by a third party, is asked to do the randomization.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran

City

tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2023-02-15, 1401/11/26

Ethics committee reference number

IR.IUMS.REC.1401.951

Health conditions studied

1

Description of health condition studied

Inflammatory Bowel Disease

ICD-10 code

K50

ICD-10 code description

Crohn's disease [regional enteritis]

2

Description of health condition studied

Inflammatory Bowel Disease

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Chronic fatigue: It is a complex disorder that lasts for

more than a month and cannot be explained by a secondary disease.

Timepoint

The results are evaluated at the beginning of the study and at the end of the 28th day.

Method of measurement

The fatigue questionnaire in IBD patients called IBD-F will be used to measure the severity and impact of fatigue on the patients' activities. Fatigue is measured in each question by scoring on a Likert scale from 0 to 4 . This questionnaire has 3 parts, which will be used in this study from parts 1 and 2.In the first part, the severity of the disease and in the second part, the impact of fatigue in these patients is examined. In the first part, the total score is between 0 and 20. If it is 0, it means no fatigue and no need to answer other parts. The second part includes a score between 0 and 120 (questions 3,4,9,12,13,14 can be answered not be given). The way to calculate the score of the second part is to divide the total score by 120, except for the mentioned questions, multiply by 4 and multiply by 120 in total. The first part has 5 questions and the second part has 30 questions.

2

Description

Quality of life: Quality of life is defined as a person's level of satisfaction with health, relaxation and participation in activities.

Timepoint

The results are evaluated at the beginning of the study and at the end of the 28th day.

Method of measurement

Short form of quality of life questionnaire for patients with inflammatory bowel disease (IBDQ-9) In this validated questionnaire, digestive, systemic, emotional and social complications of inflammatory bowel disease are evaluated. (This questionnaire contains 9 questions related to the effects of inflammatory bowel disease on a person's quality of life, each item is assigned from 1 to 7 points. The validity and reliability of the questionnaire in the Iranian population has also been investigated and confirmed.

3

Description

Disease activity is defined as reversible characteristics of the disease.

Timepoint

The results are evaluated at the beginning of the study and at the end of the 28th day.

Method of measurement

SCCAI-P Questionnaire: In this validated questionnaire, the symptoms, severity and activity of ulcerative colitis are evaluated. There are questions related to the number of bowel movements during the day and night, presence of blood in stool, general health status, Urgent bowel movements and non-gastrointestinal symptoms during the last week are included in this questionnaire.The points assigned to the answers are added up and evaluated based on the final score of disease activity. The range of points is from 0 to 19. According to this questionnaire, people with a score higher than 5 have active ulcerative colitis. sCDAI questionnaire: In this validated questionnaire, the symptoms, severity and activity of Crohn's disease are evaluated. In relation to the number of loose or watery stools, abdominal pain, general health status, use of antidiarrheal drugs, non-gastrointestinal manifestations, presence of abdominal mass, hematocrit and body weight are included in this questionnaire. The points assigned to the answers are added up and evaluated based on the final score of disease activity. The range of points is from 0 to 600. A score less than 150 indicates the recovery phase of the disease, 150 to 219 mild disease, 220 to 450 moderate disease and above 450 severe disease.

Secondary outcomes

1

Description

hand grip/ muscle strength

Timepoint

at baseline and at the end of the study

Method of measurement

normalized handgrip

Intervention groups

1

Description

Intervention group: Intervention group: daily receiving one Mg tablet containing 250 mg Mg and a Neurobion tablet containing 100 mg of vitamin B1, 100 mg of vitamin B6 and 250 mg of vitamin B12.

Category

N/A

2

Description

Control group: In the control group, one Neurobion placebo and one magnesium placebo are used daily.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

gastroentrology clinic

Full name of responsible person

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Sponsors / Funding sources

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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
Iran 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

If there is a request to use the data of this study in a meta-analysis or systematic review, the primary and secondary results of this study will be provided to the requesters in the form of joint research.

When the data will become available and for how long

Since the publication of the article resulting from this study, it will be possible to make the data available for the next two years. This time will probably be from the end of 2023 to the end of 2025.

To whom data/document is available

Known researchers from prestigious academic research centers.

Under which criteria data/document could be used

If the intellectual rights of the providers of this research are preserved and the proposed research is aimed at the goals of the current study or solving the clinical problem of the target group of this study, there is a possibility of cooperation.

From where data/document is obtainable

Direct contact with the email address or phone number of the responsible author or the administrators of this research project.

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

After the contact of the researchers, the process of accessing the data and conducting joint research with the requesters will be done for a maximum of one month.

Comments