

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Study of the effect of B1, B6 and B12 vitamins combination on pain and somatic symptoms in patient with fibromyalgia.

Protocol summary

Study aim

The purpose of this study is to investigate the effect of the combination of vitamins B1, B6 and B12 on pain and physical symptoms of patients with fibromyalgia.

Design

Phase 3 clinical trial with placebo control group, double-blind and randomized with 4 permutation blocks method, with a total sample size of 64.

Settings and conduct

This study will be conducted in subspecialty clinic of Razi hospital of Rasht under a rheumatology specialist. Diagnosis of patients is based on ACR 2010. All patients will complete and sign informed consent, then the patients will be randomized into two groups using Permuted block randomization. Patients will complete the inventories of visual analog scale, revised fibromyalgia impact questionnaire and 12 item short form health survey at the beginning of the study and 1 month later. All data will be analyzed by special statistical software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients must meet the American College of Rheumatology criteria for fibromyalgia (ACR2010). A rheumatologist confirms diagnosis of fibromyalgia. Exclusion criteria: Age younger than 18 or older than 70 years old Pregnancy. Cases of chronic liver disease, severe renal failure Breast feeding History of sensitivity to B1 vitamin, B6 vitamin and B12 vitamin Consumption of group B Vitamin supplements

Intervention groups

The intervention group will receive a combination pill containing vitamins B1, B6 and B12 once a day for one month, and the control group will receive a placebo similar to the mentioned pill once a day for one month.

Main outcome variables

Disease severity, pain intensity and quality of life in patients with fibromyalgia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041646N2**

Registration date: **2023-11-14, 1402/08/23**

Registration timing: **prospective**

Last update: **2023-11-14, 1402/08/23**

Update count: **0**

Registration date

2023-11-14, 1402/08/23

Registrant information

Name

Ashkan Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of B1, B6 and B12 vitamins combination on pain and somatic symptoms in patient with fibromyalgia.

Public title

Effect of B1, B6 and B12 vitamins on fibromyalgia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients must meet the American College of Rheumatology criteria for fibromyalgia (ACR2010). A rheumatologist confirms diagnosis of fibromyalgia.

Exclusion criteria:

Age younger than 18 or older than 70 years old
Pregnancy. Cases of chronic liver disease, severe renal failure
Breast feeding
History of sensitivity to B1 vitamin.
History of sensitivity to B6 vitamin
History of sensitivity to B12 vitamin
Consumption of group B Vitamin supplements

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to avoid bias in the selection of patients, the sequencing and distribution of patients into groups A and B is done by Statistics. Then, the type of intervention or placebo of groups A and B is done by someone outside the team of evaluators and analysts. To randomize people in two groups, the method of 4 permutation blocks is used. Considering group A and group B, the randomization process will be as follows. Randomization was done with SAS version 9 software. Seed: 67563107250670 Block sizes: 4 Actual list length: 64 block identifier, block size, sequence within block, treatment • 1, 4, 1, Group B • 1, 4, 2, Group A • 1, 4, 3, Group B • 1, 4, 4, Group A • 2, 4, 1, Group A • 2, 4, 2, Group B • 2, 4, 3, Group B Considering that the current study is double-blind, and the drug and placebo are presented to the performers and patients in similar and non-transparent envelopes, interventional concealment or the fact that groups A and B are placebos means that the allocation is concealed. For this purpose, the choice of intervention or placebo group A and B is done after distributing the names of the patients and by a person who is not aware of the sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, in order to avoid bias in the selection of patients, the sequencing and distribution of patients into groups A and B is done by Statistics specialist. Then the type of intervention or placebo group A and B is done by someone outside the team of evaluators and analysts. Also, a colleague outside the group of plan executives, evaluators and analysts is asked to pack the original drug and the placebo, which have the same appearance and quality, in the amount needed for one month (60 pieces) in exactly the same envelopes, dark and closed. place and name them as A and B according to the type of intervention or placebo, and give them to the project managers. In this way, neither the people under study nor the presenters and analysts know about the intervention and placebo groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Gilan University of medical sciences

Street address

In front of 17 Shahrivar hospital, Shahid siadati street, Namjoo avenue

City

Rasht

Province

Guilan

Postal code

4144895655

Approval date

2023-09-11, 1402/06/20

Ethics committee reference number

IR.GUMS.REC.1402.315

Health conditions studied**1****Description of health condition studied**

Pain and somatic symptoms in fibromyalgia disease

ICD-10 code

Fibromyalg

ICD-10 code description

M79.7

Primary outcomes

1

Description

disease severity.

Timepoint

Before starting the study, then one month after taking medication.

Method of measurement

revised fibromyalgia impact questionnaire

2

Description

Pain intensity.

Timepoint

Before starting the study, then one month after taking medication.

Method of measurement

visual analogue scale

3

Description

Quality of life.

Timepoint

Before starting the study, then one month after taking medication.

Method of measurement

12item short form health survey

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group includes patients with fibromyalgia who receive 100 mg of vitamin B1, 100 mg of vitamin B6 and 200 micrograms of vitamin B12 as a single tablet made by Mahban Daru company, one per day for thirty days.

Category

Treatment - Drugs

2

Description

Control group: This group includes patients suffering from fibromyalgia who receive the placebo manufactured by Subhan Daru company, which contains tablets of the same color, shape and size as the vitamin tablets received by the intervention group for one month and in the amount of one per day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital clinic

Full name of responsible person

Banafsheh Gavidel parsa

Street address

Esteghamat avenue, Razi clinic tower

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Sponsors / Funding sources

1

Sponsor

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

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

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Contact

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Person responsible for updating data

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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