Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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 of64.

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 12item 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)

Phone

+98 13 3467 2363

Email address

ashkan96shamami@gmail.com

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
City
Rasht
Province
Guilan
Postal code
4144895655
Phone
+98 13 3353 0169
Email
bghavidelparsa@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza naghi poor
Street address
Infront of 17 shahrivar hospital, Shahid siadati street, Namjoo avenue,.
City
Rasht
Province
Guilan
Postal code
4144895655
Phone
+98 13 3333 6394
Email
research@gums.ac.ir
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

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Banafshe Ghavidel parsa

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Sardr jangal avenue ,razi hospital

City
Rasht

Province
Guilan

Postal code
4144895655

Phone
+98 13 3353 0169

Email
bghavidelparsa@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Banafsheh ghavidel parsa

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Sardare jangal avenue,Razi hospital

City
Rasht

Province
Guilan

Postal code
4144895655

Phone
+98 13 3353 0169

Email
bghavidelparsa@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Banafsheh Ghavidelparsa

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

Street address
Sardare jangal avenue ,razi hospital

City
Rasht

Province
Guilan

Postal code
4144895655

Phone
+98 13 3353 0169

Email
Ashkan96shamami@gmail.com

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