Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Investigating the effect of vitamin B12 on disease severity, pain intensity and psychological symptoms of Fibromyalgia patients referred to fibromyalgia clinic of Razi hospital

Protocol summary

Study aim

This study aims to investigate the role of vitamin B12 on pain severity and psychological symptoms of fibromyalgia patients.

Design

This is a single arm, phase 3 pre-post study on 30 fibromyalgia patients. blinding is not applicable to this study.

Settings and conduct

This is a prospective study on fibromyalgia patients referred to clinic of Razi teaching hospital in Rasht, Iran. Patients must fulfill inclusion and exclusion criterias. Demographic data (including age, educational level, marital status and work status) will be obtained from all participants. All the patients will be asked to fill out the Revised Fibromyalgia Impact Questionnaire (FIQR), Short-Form Health Survey (SF-12), pain visualized analogue scale (pain VAS), Hospital anxiety and distress scale (HADS), at the initial visit. Then they will receive 50 pearls of vitamin B12 (1000mcg) and will be instructed to use one pearl daily for 50 days. To assess the effectiveness of treatment, all the questionnaires will be asked to fulfill for the second time after the treatment course is completed.

Participants/Inclusion and exclusion criteria

Patients will be included if their diagnosis is made by a rheumatologist and confirmed by American college of Rheumatology 2016 (ACR2016). They will be excluded if they are under 18 years old, suffering from comorbidities with chronic pain and inflammatory , psychological disease except depression and anxiety, or if they have vegeterian diet or history of gastrectomy or bypass surgery. they will be excluded if they don't consent to participate the trial.

Intervention groups

Patients will receive a daily dose of 1000microgram vitamin B12 for 50 days.

Main outcome variables

Main outcomes will be FIQR for assessing disease severity, SF-12 to assess health related quality of life, pain VAS for perceived pain intensity by patients and HADS for psychological evaluation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200920048782N1**
Registration date: **2021-08-28, 1400/06/06**
Registration timing: **prospective**

Last update: **2021-08-28, 1400/06/06**
Update count: **0**

Registration date

2021-08-28, 1400/06/06

Registrant information

Name

Faeze Gharibpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3357 2495

Email address

faezegharibpoor@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of vitamin B12 on disease severity, pain intensity and psychological symptoms of Fibromyalgia patients referred to fibromyalgia clinic of Razi hospital

Public title
Effect of vitamin B12 on pain and psychological symptoms of Fibromyalgia patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with fibromyalgia diagnosis based on a rheumatologist's opinion Fulfilled American college of rheumatology 2016 (ACR 2016)
Exclusion criteria:
Patients under 18 years old Being pregnant or breast feeding Patients suffering from comorbidities with chronic pain or inflammation(e.g., recent trauma, malignancy, other rheumatic diseases, celiac disease, inflammatory bowel disease) Patients with psychological disorders except depression and anxiety Patients with history of gastrectomy or bypass surgery Patients with vegeterian diet Patients without consent to participate the study
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
this is a pre-post study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Guilan university of medical sciences
Street address
Student Research Committee, Deputy of Research and Technology, Namjoo St
City
Rasht
Province
Guilan
Postal code
4144666949
Approval date
2021-07-28, 1400/05/06
Ethics committee reference number
IR.GUMS.REC.1400.197

Health conditions studied

1

Description of health condition studied
Fibromyalgia
ICD-10 code
M79.7
ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description
Disease severity
Timepoint
Before intervention and 50 days after intervention
Method of measurement
Revised Fibromyalgia Impact Questionnaire

2

Description
Psychological symptom
Timepoint
Before intervention and 50 days after intervention
Method of measurement
Hospital anxiety and depression scale

3

Description
Pain intensity
Timepoint
Before intervention and 50 days after intervention
Method of measurement
Visual analogue scale

4

Description
Health related quality of life
Timepoint
Before intervention and 50 days after intervention
Method of measurement
Short-Form Health Survey

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients will receive 50 pearls of vitamin B12 (1000mcg, Health aid company, England) and will be instructed to use one pearl daily for 50 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Razi teaching hospital
Full name of responsible person
Banafsheh Ghavidel-parsa
Street address
Balal zadeh st
City
Rasht
Province
Guilan
Postal code
9565541448
Phone
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Email
Bghavidelparsa@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan university of medical sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
Deputy of Research and Technology, Namjoo St
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Rasht
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Guilan
Postal code
4144666949
Phone
+98 13 3333 5820
Email
Nemati@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan 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
Rasht University of Medical Sciences
Full name of responsible person
Faeze Gharibpoor
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

all data except data revealing patients' identities can be available if requested for reasonable cause.

When the data will become available and for how long

after publication

To whom data/document is available

to researchers with reasonable cause

Under which criteria data/document could be used

for meta analysis or additional analysis of data

From where data/document is obtainable

via email address

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

sending request with proper reason to corresponding author

Comments