

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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 vegetarian 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 vegetarian 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

+98 13 3354 1001

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

City

Rasht

Province

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

Street address

No. 33, gohari alley, moalem blv

City

Rasht

Province

Guilan

Postal code

4155646515

Phone

+98 13 3357 2495

Fax**Email**

faezegharibpoor@gmail.com

Person responsible for scientific 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
Street address
No. 33, gohari alley, moalem blv
City
Rasht
Province
Guilan
Postal code
4155646515
Phone
+98 13 3357 2495
Fax
Email
faezegharibpoor@gmail.com

Person responsible for updating data

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
Street address
No. 33, gohari alley, moalem blv
City
Rasht
Province
Guilan
Postal code
4155646515
Phone

+98 13 3357 2495

Fax
Email
faezegharibpoor@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

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