Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Comparison the effectiveness of vitamin B6 and placebo in pain, psychological symptoms and inflammatory biomarkers of patients with fibromyalgia

Protocol summary

Study aim

Investigating the role of vitamin B6 on pain, psychological symptoms and inflammatory markers of fibromyalgia patients.

Design

A concealed, randomized, double blinded, controlled trial with a paralled placebo group design of 90 fibromyalgia patients between 2021 and 2022. www.Randomization.com will be used for randomization.

Settings and conduct

This is a study on fibromyalgia patients of fibromyalgia clinic of Razi hospital, Rasht. at first visit, an IV blood sample will be collected from participants and will be analyzed for inflammatory markers. participants will also fulfill required questionnaires. then, they will receive either placebo or drug(in completely identical bottles) according to their disease severity and produced sequence. patients will be instructed to take 2 tablets each day for 2 months. after the completion of treatment course, at the final visit, blood samples will be collected and same markers will be analyzed.same questionnaires will be fulfilled, as well. except for analyst, no other person is aware of bottles' containment.

Participants/Inclusion and exclusion criteria

Participants will fibromyalgia patients whom diagnosis is based on a rheumatologist's opinion and American college of rheumatology (ACR2016). Patients will be excluded if they are under 18 years old, pregnant or breast feeding; patients suffering from comorbidities with chronic pain or inflammation , patients with psychological disorders except depression and anxiety, or patients without consent to participate the study.

Intervention groups

Vitamin B6 (40mg) or placebo, twice daily for 60 days.

Main outcome variables

FIQR (revised fibromyalgia impact questionnaire), SF-12 (short-form health survey), HADS (hospital anxiety and depression scale), Pain-VAS (pain visual analogue scale), ESR, PDW (platelet distribution width), MPV (mean platelet volume), NLR (neutrophil leukocyte ratio)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200920048782N2**
Registration date: **2021-10-04, 1400/07/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-04, 1400/07/12**
Update count: **0**

Registration date

2021-10-04, 1400/07/12

Registrant information

Name
Faeze Gharibpoor
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 13 3357 2495
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faezegharibpoor@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effectiveness of vitamin B6 and placebo in pain, psychological symptoms and inflammatory biomarkers of patients with fibromyalgia

Public title
Effect of vitamin B6 in treatment of fibromyalgia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with fibromyalgia diagnosis based on a rheumatologist opinion fulfilled American college of rheumatology 2016 criteria (ACR 2016)
Exclusion criteria:
Patients under 18 years old Being pregnant or breastfeeding Patients suffering from comorbidities with chronic pain and inflammation (e.g., recent major trauma, malignancy, other rheumatic disease) Patients with psychological disorders except depression and anxiety Patients without consent to participate the study
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Using stratified randomization, Patients will be assigned to three strata based on their disease severity, which is obtained from Revised fibromyalgia impact questionnaire (mild:0-39, moderate: 40-59, severe: 60-100). Thereafter, through permuted block randomization, 3 blocks, each containing 30 participants will be formed. Each strata has one block with 30 patients with equal distribution (15 patients from interventional group and 15 patients from placebo). Random sequence will be generated using www.Randomization.com. For allocation concealment, sequentially numbered, sealed, opaque envelops will be used. patients, will be initially evaluated for their disease severity and will receive either bottle A or B, according to their strata sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
Active drug and placebo will be kept in completely identical (in shape, color, size and taste) plum bottles, codded as either A or B. No other person, except for the statistical analyst, including participants, principal investigator, physician, data collectors, outcome assessors, and manuscript writers are not aware of the bottles' content. Statistical analyst doesn't have any involvement in the process of the study and will join the study when the data gathering process is completely finished.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethic committes 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
2021-09-15, 1400/06/24
Ethics committee reference number
IR.GUMS.REC.1400.258

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 60 days after intervention
Method of measurement
Revised fibromyalgia impact questionnaire (FIQR)

2

Description
Psychological symptoms
Timepoint
Before intervention and 60 days after intervention
Method of measurement
Hospital anxiety and depression scale (HADS)

3

Description
Pain intensity
Timepoint
Before intervention and 60 days after intervention
Method of measurement
Pain visual analogue scale (VAS)

4

Description
Health related quality of life
Timepoint
Before intervention and 60 days after intervention
Method of measurement
Short-form health survey (SF-12)

5

Description
Inflammation
Timepoint
Before intervention and 60 days after intervention
Method of measurement
ESR

6

Description
Inflammation
Timepoint
Before intervention and 60 days after intervention
Method of measurement
Platelet distribution width (PDW)

7

Description
Inflammation
Timepoint
Before intervention and 60 days after intervention
Method of measurement
Mean platelet volume (MPV)

8

Description
Inflammation
Timepoint
Before intervention and 60 days after intervention
Method of measurement
Neutrophil leukocyte ratio (NLR)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive pills of vitamin B6 (40mg, Iran homone company) twice daily, for 60 days
Category
Treatment - Drugs

2

Description
Control group: Patients will receive pills with same shape as vitaminB6 (lactose monohydrate(78%), corn starch(20%), aerosil (0.5%), talc (1%) and magnesium stearate (0.5%), produced under standard condition by Pharmacology faculty of Guilan university of medical sciences), twice daily for 60 days.
Category
Placebo

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
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Rasht

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4144666949
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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
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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