Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of vitamin D on quality of life in fibromyalgia pateints

Protocol summary

Summary

Aim: Evaluation the effect of vitamin D supplementation on quality of life in fibromyalgia syndrome. Study populations: Patients between 20-70 years with fibromyalgia who referred to the rheumatology clinic of Firouzgar hospital. Sample size: 45 patients in each group. Inclusions: fibromyalgia patients who are vitamin D deficient .Exclusions: history of rheumatic diseases, diabetes, under treatment of psychologist. Intervention: Serum 25OH D will be measured in all patients. patients with age between 20- 70 years and serum levels of vitamin D, less than 30ng/ml and desire to stop taking sleep medications and in the loss of exclusion criteria will enter in the study and demographic information as well as questionnaires EQ-5D-3L. SF36.FIQ PSQI will be completed. Then patients will be divided into two groups. Group 1 treated with vitamin D 50000IU Weekly and Trazodon (25mg at night while sleeping) and Group 2 will receive trazodon (25mg at night while sleeping) without vitamin D . Patients will be re-evaluated 4 and 8 weeks after intervention and the level of vitamin D will be measured again, in addition to completing checklists again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100610960N2**
Registration date: **2012-12-31, 1391/10/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-12-31, 1391/10/11

Registrant information

Name

Mozhdeh Zabihiyeganeh

Name of organization / entity

Tehran university of medical scienses

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1301

Email address

m-zabihi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2013-03-19, 1391/12/29

Expected recruitment end date

2014-03-19, 1392/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D on quality of life in fibromyalgia pateints

Public title

Effect of vitamin D on quality of life in fibromyalgia pateints

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-70 years old females who fill ACR criteria 2010 of fibromyalgia and 25OHD level less than 30 ng/ml. Exclusions: rheumatologic disease; metabolic bone disease; diabetes; major depression; liver diseases; chronic kidney disease; cancer; malabsorption; pregnancy; steroid user; any extra-protocol vitamin D consumption; patients who had been treated with trazodon previously with no response.

Age
From **20 years** old to **70 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran university of medical sceinces
Street address
6 floor, Tehran university of medical sceinces, Ghods street, Keshavarz blvd.
City
Tehran
Postal code
Approval date
2012-10-20, 1391/07/29
Ethics committee reference number
1391/210/14835/ɔ

Health conditions studied

1

Description of health condition studied
fibromyalgia syndrome
ICD-10 code
M79.7
ICD-10 code description
Other soft tissue disorders, not elsewhere classified

Primary outcomes

1

Description
Quality of life
Timepoint
On the day of recruitment ,4 and 8 weeks later
Method of measurement
SF36 and EQ-5D questionere

Secondary outcomes

1

Description
Rising of 25OH D level, comparison of sleep questioneer score before and after intervention in each group.
Timepoint
on 1st day of recuitment, 4 and 8 weeks after intervention.
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: Trazodone plus Vitamin D Trazodon 25 mg daily plus pearl vitamin D 50000 unit weekly for 8 weeks.
Category
Treatment - Drugs

2

Description
Control : Tab trazodon 25mg daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firouzgar hospital
Full name of responsible person
Mozhdeh Zabihi
Street address
Firouzgar hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotohi
Street address
Corner of Ghoods street, Keshavarz blvd

City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran university of medical sciences
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty