Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Evaluation of the effect of cognitive-behavioral therapy on the serum TNF-α, IL-8, IL-6, total oxidant status, and total antioxidant capacity of fibromyalgia patients in comparison with Duloxetine treatment

Protocol summary

Study aim

In this study, the effect of cognitive-behavioral therapy on the serum TNF-α, IL-8, IL-6, total oxidant status, and total antioxidant capacity of fibromyalgia patients will be evaluated and compared with the effect of medication (duloxetine) and no treatment.

Design

Clinical trial with control group, parallel groups, single blinded, randomized.

Settings and conduct

In this study which will be performed in Shafa Orthopedic Hospital, the serum level of TNF-α, IL-8, and IL-6 will be assessed before and after the intervention in three groups and the changes will be evaluated. The intervention type will be concealed form the main investigator who will do the tests and analyse the data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The diagnosis of fibromyalgia according to the criteria of American college of Rheumatology (2010) Exclusion criteria: Vitamin D deficiency; No previous history of fibromyalgia treatment; Metabolic disease; Diabetes Mellitus; mental illnesses; Other rheumatologic disorders; hepatic diseases; chronic renal disorders; heart diseases; Malnutrition; and cancer.

Intervention groups

The fibromyalgia patients will be divided into the 3 study groups. For the first group, cognitive behavioral therapy will be performed in 20 sessions (once a week). The maximum number of patients in each group will be five patients. For the second group, deloxetine (60 mg/day) will be administered for 5 months. The control group will receive no therapy.

Main outcome variables

Serum level of TNF-α, IL-8, IL-6, total oxidant status, and total antioxidant capacity

General information

Reason for update

A number of primary outcome measures have been added to the project.

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120530871N3**
Registration date: **2016-12-18, 1395/09/28**
Registration timing: **prospective**

Last update: **2021-04-19, 1400/01/30**
Update count: **2**

Registration date

2016-12-18, 1395/09/28

Registrant information

Name
Alireza Mirzaei
Name of organization / entity
Iran University of Medical Sciences
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Iran (Islamic Republic of)
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+98 21 3354 2000
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mirzaei.ar@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of cognitive-behavioral therapy on the serum TNF-α, IL-8, IL-6, total oxidant status, and total antioxidant capacity of fibromyalgia patients in comparison with Duloxetine treatment

Public title

Evaluation of the effect of cognitive bahavioral therapy on fibromyalgia patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The diagnosis of fibromyalgia according to the criteria of American college of Rheumatology (2010) Exclusion criteria:

Exclusion criteria:

Vitamin D deficiency. Patients with the history of fibromyalgia treatment. Metabolic disease; Diabetes Mellitus; mental illnesses; Other rheumatologic disorders; hepatic diseases; chronic renal disorders; heart diseases; Malnutrition; and cancer.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization of the patients into the 3 study groups will be performed by a computer-generated random number list prepared by an investigator with no clinical and labaratory involvement in the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

The main investigator who analyzes the data will be kept blinded from the type of treatment each patient receives.

Placebo

Not used

Assignment

Parallel

Other design features

Randomization has been performed by the table random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2016-12-11, 1395/09/21

Ethics committee reference number

IR.IUMS.REC 1395.95-03-196-29435

Health conditions studied

1

Description of health condition studied

Fibromyalgia

ICD-10 code

M79.7

ICD-10 code description

Fibromyalgia

Primary outcomes

1

Description

IL-8

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

ELISA

2

Description

TNF-α

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

ELISA

3

Description

IL-6

Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
ELISA

4

Description
Serum total oxidant status
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Colorimetric assay

5

Description
Serum total antioxidant capacity
Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
Colorimetric assay

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Cognitive behavioral therapy in 20 sessions
Category
Treatment - Other

2

Description
Intervention group 2: (Medication, 60 mg/day, 5 months)
Category
Treatment - Drugs

3

Description
Control group: No treatment
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Orthopedic Hospital
Full name of responsible person
Alireza Mirzaei
Street address
Shafa Orthopedic Hospital, Mojahedin Islam Avenue, Shohada Square
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mirzaeialireza26@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Naserbahkt
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Shahid Hemmat Highway
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Phone
+98 21 86701
Email
adminsite@iums.ac.ir
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person

Alireza Mirzaei

Position
Assistant Professor/ PhD

Latest degree
Ph.D.

Other areas of specialty/work
Orthopedics

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All participants' data is shareable after deidentification.

When the data will become available and for how long
6 months after the publication.

To whom data/document is available
People working in academic institutions

Under which criteria data/document could be used
The data could only be used for the evaluation of the accuracy of the results.

From where data/document is obtainable
From email address: mirzaeialireza26@gmail.com

What processes are involved for a request to access data/document
Sending an email to the due address

Comments