Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Acupuncture and Fluoxetine in the relief of pain in the patients with Fibromyalgia Syndrome (A clinical trial)

Protocol summary

Summary

The purpose of this study was to evaluate acupuncture effect on Fibromyalgia in Iranian patients and compare with effect of Fluoxetine. This is a clinical trial study on the 30 outpatients with diagnosis of FMS referring clinics of Shiraz University of Medical Sciences. The patients were randomly assigned into acupuncture (study group) or Fluoxetine (control group). Patients in control group received Fluoxetine, 20 mg capsule every morning for 8 weeks. In acupuncture group, specific acupoints were needeled three times weekly for two weeks. Severity of symptoms measured through VAS and FIQ was measured at the baseline and 2, 4, and 8 weeks after the initiation of the interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902013767N1**
Registration date: **2010-06-03, 1389/03/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-06-03, 1389/03/13

Registrant information

Name

Mohsen Hoseinzade parizi

Name of organization / entity

physical Medicine

Country

Iran (Islamic Republic of)

Phone

+98 71 1231 9040

Email address

parizim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University Of Medical Sciences

Expected recruitment start date

2008-07-06, 1387/04/16

Expected recruitment end date

2010-01-05, 1388/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Acupuncture and Fluoxetine in the relief of pain in the patients with Fibromyalgia Syndrome (A clinical trial)

Public title

Comparison of Acupuncture and Fluoxetine in the relief of pain in the patients with Fibromyalgia Syndrome (A clinical trial)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: history of the presence of at least 3 months of widespread pain that is bilateral, on the both above and below the waist, pain on palpation of at least 11 of 18 predefined tender points Exclusion Criteria: abnormal lab data, night employment

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Shiraz University of Medical Sciences
Street address
Shiraz University Of Medical Sciences
City
Shiraz
Postal code
14336-71348
Approval date
empty
Ethics committee reference number
CT-88-5035

Health conditions studied

1

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

Primary outcomes

1

Description
Pain
Timepoint
Baseline and 2, 4, and 8 weeks after intervention
Method of measurement
VAS & FIQ

Secondary outcomes

1

Description
Fibromyalgia signs and symptoms
Timepoint
Baseline and 2, 4, and 8 weeks after intervention
Method of measurement
via VAS & FIQ questionnaire

Intervention groups

1

Description
Fluoxetine, 20 mg capsule every morning for 8 weeks
Category
Treatment - Drugs

2

Description
Acupuncture at specific acupoints, three times weekly for two weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Dr. Mohammad Javad Hadianfard
Street address
Zand Ave.
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz Univesity Of Medical Sciences
Full name of responsible person
dr. Dabaghmanesh
Street address
7th Floor, Central Building of Shiraz University of Medical sciences, Zand ave., Shiraz, Iran
City
Shiraz
Grant name
فصل دوم برنامه تحقیقاتی
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz Univesity 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

Shiraz University Of Medical Science

Full name of responsible person

Dr.Mohammad Javad Hadianfard

Position

daneshyar

Other areas of specialty/work

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Person responsible for updating data

Contact

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Dr. Mohammad Javad Hadianfard

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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