

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

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

Protocol summary

parizim@sums.ac.ir

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 needed 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.

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

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

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 University 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
Street address
Zand ave
City
Shiraz
Postal code
71348-46374
Phone
+98 71 1231 9040
Fax
Email
hadianj@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University Of Medical Science
Full name of responsible person
Mohammad Javad Hadian fard
Position
daneshyar
Other areas of specialty/work
Street address

Zand Ave Shahid Faghihi hospital
City
Shiraz
Postal code
71348-14336
Phone
+98 71 1231 9040
Fax
Email
hadianj@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Javad Hadianfard
Position
Associate Professor
Other areas of specialty/work
Street address
Shahid Faghih hospital, Zand Ave.
City
Shiraz
Postal code
71348-46374
Phone
+98 71 1231 9040
Fax
Email
hadianj@sums.ac.ir
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