Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy Comparison of Acupuncture with Fluoxetine in Symptom Controlling of Fibromyalgia Patients

Protocol summary

Summary

Study Goal: Efficacy Comparison of Acupuncture with Fluoxetine in Symptom Controlling of Fibromyalgia Patients Study Design: Randomized; Drug Control; Single Recruitment Center Target Sample: Patients Referring from Rheumatology Clinic of Emam Reza Hospital of Tabriz Medical University Inclusion criteria: Diagnostic criteria for Fibromyalgia based on American College of Rheumatology ACR (Wolfe et al 1990) Exclusion Criteria: Inflammatory Rheumatic Joint Disease; Myopathies; Myositis; Infections; Tumors; Endocrine Diseases Target Sample Size: A Total of 90 Cases; Randomly Divided into 3 Groups Interventions: Group A: Acupuncture 10 Sessions; Twice a week Group B: Acupuncture and Fluoxetine 10 mg/day Group C: Control Group; Fluoxetine 10 mg/day Primary Outcome Measure: Symptoms of Fibromyalgia Syndrome Primary Outcome Method of Measurement: Health Assessment Questionnaire SF-36; Fibromyalgia Impact Questionnaire FIQ; Visual Analogical Scale VAS Primary Outcome Time Point: Before Intervention; 5 Weeks after beginning intervention; 2 Months after finishing intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107026934N1**
Registration date: **2012-01-16, 1390/10/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-16, 1390/10/26

Registrant information

Name

Susan Kolahi

Name of organization / entity

Tabriz Medical Science University

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Recruitment status

Recruitment complete

Funding source

Holistic Medicine Association of Eastern Azerbaijan Province

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy Comparison of Acupuncture with Fluoxetine in Symptom Controlling of Fibromyalgia Patients

Public title

Comparison of Acupuncture with Fluoxetine in Treatment of Fibromyalgia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Diagnostic Criteria for Fibromyalgia Based on American College of Rheumatology ACR (Wolfe et al 1990) Exclusion Criteria: Inflammatory Rheumatic Joint Disease; Myopathies; Myositis; Infections; Tumors; Endocrine Diseases

Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
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
Ethics Committee of Tabriz Medical Science University
Street address
Tabriz Medical Science University, Golgasht st.
City
Tabriz
Postal code
Approval date
2011-09-23, 1390/07/01
Ethics committee reference number
9033

Health conditions studied

1

Description of health condition studied
Fibromyalgia
ICD-10 code
M79.7
ICD-10 code description
Fibromyositis; Fibrositis; Myofibrositis

Primary outcomes

1

Description
Symptoms of Fibromyalgia Syndrome
Timepoint
Before intervention; 5 Weeks after beginning intervention; 2 Months after finishing intervention
Method of measurement
Health Assessment Questionnaire SF-36; Fibromyalgia Impact Questionnaire FIQ; Visual Analogical Scale VAS

Secondary outcomes

empty

Intervention groups

1

Description
Group A: Acupuncture; 10 sessions; twice a week
Category
Other

2

Description
Group B: Acupuncture and Fluoxetine 10 mg/day
Category
Treatment - Drugs

3

Description
Group C: Control group; Fluoxetine 10 mg/day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology Clinic of Emam Reza Hospital, Tabriz Medical Science University
Full name of responsible person
Mohama Tabatabaee, MD
Street address
Tabriz Medical Science University, Emam Reza Hospita,lGolgasht st.
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Holistic Medicine Association of Eastern Azerbaijan Province
Full name of responsible person
Mohamad Zahednia,MD
Street address
Holistic Medicine Association of Eastern Azerbaijan Province,No.38, 17th. shahrivar st.

City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Holistic Medicine Association of Eastern Azerbaijan Province
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

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Person responsible for updating data

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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