

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

kolahis@tbzmed.ac.ir

##### 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,IGolgasht st.

**City**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Holistic Medicine Association of Eastern Azerbaijan Province

**Full name of responsible person**

Mohamad Zahednia,MD

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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

**Contact**  
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Holistic Medicine Association of Eastern Azerbaijan Province

**Full name of responsible person**  
Mohammad Tabatabaee, MD

**Position**  
Physician; Project Colleague

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## Person responsible for scientific inquiries

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Rheumatologist; Assistant Professor

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## Person responsible for updating data

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Physician, Project Colleague

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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*