

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of the efficacy of acupuncture and medication therapy with drug therapy alone in improving anxiety syndrome in patients referred to the outpatient clinic of Ibn Sina Hospital

Protocol summary

Study aim

Determining the effectiveness of adding acupuncture to the usual treatment of anxiety through clinical evaluation (psychometrics) and laboratory

Design

A clinical trial with a control group, a randomized, two blinded, With parallel groups

Settings and conduct

Patients with anxiety symptom referring to Ibne sina Psychiatric Clinic are divided into three groups. The first group is treated with drug therapy + acupuncture in the second group drug and of placebo acupuncture and the third group of drug therapy alone.

Participants/Inclusion and exclusion criteria

Diagnosis of anxiety disorder (other than phobias) based on examination, age of 18-60 years, non-use of psychotropic substances and other simultaneous psychiatric disorder

Intervention groups

First treatment group: Treatment with sertraline with a dose of 50 mg per day for 8 weeks and 12 sessions of acupuncture
Second intervention group: Treatment with sertraline with a dose of 50 mg per day for 8 weeks
Control group: Treatment with sertraline at a dose of 50 mg / day for 8 weeks and 12 sessions of placebo acupuncture

Main outcome variables

The effect of acupuncture on anxiety syndrome in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181031041511N1**

Registration date: **2018-12-02, 1397/09/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-02, 1397/09/11**

Update count: **0**

Registration date

2018-12-02, 1397/09/11

Registrant information

Name

Amir Rezaei ardani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2701

Email address

rezaeia@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of acupuncture and medication therapy with drug therapy alone in improving anxiety syndrome in patients referred to the outpatient clinic of Ibn Sina Hospital

Public title

Study of the efficacy of adding acupuncture to drug therapy in patients with anxiety syndrome referring to outpatient clinics of Ibn Sina Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Detection of anxiety disorder based on examination No other psychiatric disorder Non-use of psychotropic substances other than cigarettes

Exclusion criteria:

Use of another drug that may interfere Unwillingness to attend the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are selected through available sampling. They are randomly assigned to the case and control group according to the random numbers table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants include the first group of acupuncture and the second group receiving acupuncture, and the patients themselves do not know which group is included. The placebo needle is in such a way that the patient feels it, but the needle is removed from the upper part of the patient instead of entering the patient's body), the principal researcher and the evaluator also identify the patients for acupuncture and do not know which acupuncture or placebo they do). Only the acupuncture practitioner is informed of the groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

•Ethics committee of mashhad University of Medical Sciences

Street address

Ibne sina hospital , Hore ameli Ave , Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

919583134

Approval date

2017-08-23, 1396/06/01

Ethics committee reference number

IR.MUMS.sm.Rec.1396.239

Health conditions studied

1

Description of health condition studied

Generalized anxiety, social anxiety, panic disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Decrease of 50% of Spielberger test scores of anxiety and decrease of serum cortisol level at the end of 8 weeks compared to control group

Timepoint

The beginning of the study and the Eighth week

Method of measurement

Spielberger Anxiety Inventory and Cortisol Serum Assay

Secondary outcomes

empty

Intervention groups

1

Description

first Intervention group: Intervention group: Treatment with sertraline with a dose of 50 mg per day for 8 weeks and 12 sessions of acupuncture

Category

Treatment - Other

2

Description

Control group: Control group: Treatment with sertraline at a dose of 50 mg / day for 8 weeks and 12 sessions of placebo acupuncture

Category

Treatment - Other

3

Description

Second intervention group: Treatment with sertraline with a dose of 50 mg per day for 8 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibne sina hospital

Full name of responsible person

amir rezaei ardani

Street address

Ibne sina hospital , Hore ameli Ave , mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

mohsen tafaghodi

Street address

Deputy of Research and Technology
University, Opposite no.18, Danshgah Ave, mashhad

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

ali khorsand vakilzade

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Acupuncture and Supplement

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Amir Rezaei ardani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

ali sabagh gol

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Spielberger test score and serum cortisol levels

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

All researchers are able to access the study results

Under which criteria data/document could be used

Unidentifiable information is not shared with another organization

From where data/document is obtainable

amir rezaei ardani . rezaeia@mums.ac.ir

What processes are involved for a request to access data/document

Study data is published in the course of the paper and no other personal data is available to applicants

Comments