Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Study of effect of adding acupuncture to Methylphenidate in treatment of attention deficit hyperactivity disorder(ADHD) in children and adolescents

Protocol summary

Study aim
The evaluation of efficacy of adding acupuncture to Methylphenidate in treatment of attention deficit hyperactivity disorder in children and adolescents

Design
A randomized, double blinded, sham controlled clinical trial with a parallel group design of 90 patients

Settings and conduct
This study was conducted on patients with confirmed ADHD referred to Ibn-e-Sina Psychiatric Hospital, Mashhad, Iran between January 2017 and June 2017. Patients were randomly allocated into acupuncture (experimental group) or sham acupuncture (control group). All patients received a standard treatment of 0.3-1 mg/kg of Methylphenidate (Ritalin) in 2 or 3 divided doses. Before the intervention patients were evaluated using home version of ADHD-rating scale (RS) and Continuous Performance Test. Then within 4 weeks the intervention group received acupuncture treatment 3 times a week. Sham acupuncture was used for the control group within the same duration as acupuncture group. The treatment outcomes were measured using home version of ADHD-rating scale (RS) and Continuous Performance Test after 3 weeks. Patients, their parents, child and adolescent psychiatrist and the psychologist who performed before-after tests were not aware of grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 6 to 18 year old patients with the diagnosis of ADHD by DSM-5 criteria who are on the standard treatment with Methylphenidate or Methylphenidate and Clonidine without any dose change from 2 weeks before the study and during the study
Exclusion criteria: patients with mental retardation, epilepsy, pervasive developmental disorders, schizophrenia, manic episode, mood and anxiety disorders and drug or organic disorder induced hyperactivity

Intervention groups
Acupuncture (experimental group) and sham acupuncture (control group)

Main outcome variables
Score of ADHD-rating scale; score of CPT

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2015091121852N1**
Registration date: **2016-11-27, 1395/09/07**
Registration timing: **prospective**

Last update: **2018-03-11, 1396/12/20**
Update count: **1**

Registration date
2016-11-27, 1395/09/07

Registrant information

Name
Mahsa Nahidi

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Mashhad University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

2016-12-21, 1395/10/01

Actual recruitment end date

2017-06-20, 1396/03/30

Trial completion date

empty

Scientific title

A Study of effect of adding acupuncture to Methylphenidate in treatment of attention deficit hyperactivity disorder(ADHD) in children and adolescents

Public title

Acupuncture in treatment of attention deficit hyperactivity disorder in children and adolescents

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Written and oral informed consent by parents of participants Age between 6 to 18 years The diagnosis of ADHD according to DSM-5 criteria by a child and adolescent psychiatrist Being on the standard treatment with Methylphenidate or Methylphenidate and Clonidine without any dose changes from 2 weeks before and during the study period

Exclusion criteria:

Patients with mental retardation, epilepsy, pervasive developmental disorders, schizophrenia, manic episode, mood and anxiety disorders and drug or organic disorder induced hyperactivity Any dose change in the standard drug therapy during the study period

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by using a random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization was done by a researcher who was not aware of the study protocol and outcomes. Patients and their parents, as well as child and adolescent psychiatrist were not aware of grouping, Moreover, the psychologist, who was the researcher-in-charge of before-after tests, was not aware of interventions. Also, the outcomes of the study were recorded by the psychiatrist who made no other contribution to the study.

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

Ghoreshi building, Daneshgah St., Mashhad, Khorasan Razavi, Islamic Republic of Iran

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Province

Razavi Khorasan

Postal code

1394491388

Approval date

2015-06-24, 1394/04/03

Ethics committee reference number

IR.MUMS.fm.REC.1394.61

Health conditions studied

1

Description of health condition studied

Attention Deficit Hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

ADHD Rating Scale score

Timepoint

Before the intervention and 3 weeks after the intervention

Method of measurement

ADHD Rating Scale-IV questionnaire

2

Description

Continuous Performance Test score

Timepoint

Before the intervention and 3 weeks after the intervention

Method of measurement

Continuous Performance Test

Secondary outcomes

empty

Intervention groups

1

Description

Patient group will receive acupuncture for 12 sessions(three 40 minute sessions weekly).

Category

Treatment - Other

2

Description

Control group will receive sham acupuncture for12 sessions(three 40 minute sessions weekly).In this group special needles are used that do not enter the skin and acupoints are different from the patinent group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebne Sina Hospital Outpatient Clinics

Full name of responsible person

Mahsa Nahidi

Street address

Hor-e-Ameli Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Affairs of Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Fayyazi Bordbar

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Ghoreishi building, ,Daneshgah St., Mashhad, Khorasan Razavi

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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

Research Affairs of 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

Mahsa Nahidi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Clinical Study Report
Undecided - It is not yet known if there will be 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