

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of efficacy of auricular acupuncture with a control group in childhood with Attention-deficit/hyperactivity disorder

Protocol summary

Study aim

Comparison of the effect of auricular acupuncture with the control group in children with ADHD

Design

In this phase 1-2 single blind randomized clinical trial, 30 children are randomly assigned to intervention and control groups. Intervention is performed 4 times with an interval of 1 week.

Settings and conduct

The study setting is the childcare centers is affiliated with the Tehran Welfare Organization. Blindness is only done for patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 6-14-year-old children with ADHD Non-inclusion criteria: the history of epilepsy; schizophrenia; mental retardation (IQ less than 70); active depression; autism.

Intervention groups

Intervention group1: Auricular acupuncture with electrical stimulation. Intervention group 2: The seeds are placed on the ear on non-acupuncture points and are not stimulated.

Main outcome variables

Symptoms severity was assessed using the Conners and CSI questionnaire; Changes in the symptoms of illness from the point of view of teachers.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090527001957N9**
Registration date: **2019-09-30, 1398/07/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-30, 1398/07/08**

Update count: **0**

Registration date

2019-09-30, 1398/07/08

Registrant information

Name

Fataneh Hashem Dabaghian

Name of organization / entity

Research Institute for Islamic and Complementary Medicine

Country

Iran (Islamic Republic of)

Phone

+98 21 3395 0152

Email address

fatanehdabaghian@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of auricular acupuncture with a control group in childhood with Attention-deficit/hyperactivity disorder

Public title

auriculotherapy and ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 6-14 years diagnosis of ADHD based on DSM- V criteria informed consent of patients or their parents If medication, education, occupational and psychological therapy are used, there has been no change in drug dosage or treatment or symptoms of ADHD for at least the past 2 weeks.

Exclusion criteria:

History of epilepsy schizophrenia neurological disorders any psychological disorder requires medication hyperthyroidism

Age

From **6 years** old to **14 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

A list is generated using a random number table and intervention A and B are assigned one by one. Sealed envelopes are used for allocation concealment, with the patient number on the envelope and the name of the intervention group inside the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the intervention group, acupuncture seeds are placed at the acupuncture point of the ear and electrical stimulation is performed. In the control group, the seeds are placed on the non-acupuncture point on ear and no stimulation is performed. Patients are unaware of the type of interventions.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, next to Milad tower, Himmat highway

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.579

Health conditions studied

1

Description of health condition studied

attention deficit hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

severity of ADHD disorder

Timepoint

1 and 3 weeks after intervention

Method of measurement

Caner's and CSI questionnaire

Secondary outcomes

1

Description

changes of the disease severity from the viewpoint of teachers

Timepoint

3 weeks after intervention

Method of measurement

symptom severity checklist

Intervention groups

1

Description

Intervention group: Acupuncture seeds are placed at the specific site of the disease and electrical stimulation is performed once a week for 4 weeks. In case of falling seed, stimulation is done twice a week.

Category

Treatment - Other

2

Description

Control group: Acupuncture seeds are attached to non-acupuncture points on the ear and no electrical stimulation is performed.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Balandegan Adham center

Full name of responsible person

Tayebeh Aghahoseini

Street address

NO: 11, Agahi St., Dabestan Ave.,

City

Tehran

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1631766411

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+98 21 8846 9624

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balandegan@yahoo.com

2

Recruitment center

Name of recruitment center

Shahid Ghodoosi center

Full name of responsible person

Jamileh Soofi

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No: 14, Baradaran Tabrizi St., Yaser crossroad,
Niavaran St.

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3

Recruitment center

Name of recruitment center

Zanjire Mehr Mandegar

Full name of responsible person

Mohammad Pahlevan

Street address

No: 36, Taher St., North Majidieh Ave.

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1032084981

Phone

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4

Recruitment center

Name of recruitment center

Bonyade Kosar

Full name of responsible person

Batul Sarlak

Street address

NO: 44, Baghestan St., Ahmadi St., Shahid Ebrahimi
St., Darakeh Ave.

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1983833351

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Email

sarlakB@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Islamic and Complementary
Medicine

Full name of responsible person

Ali Ghobadi

Street address

No: 9, Pirnia alley, Lalehzar-no St., Jomhuri Ave.

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1145847311

Phone

+98 21 3395 0154

Email

alighobadi56@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Institute for Islamic and Complementary
Medicine

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**

Iran University of Medical Sciences

Full name of responsible person

Fataneh Hashem-Dabaghian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Others

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Research Institute for Islamic and Complementary
Medicine

Full name of responsible person

Fataneh Hashem-Dabaghian

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Person responsible for updating data**Contact****Name of organization / entity**

Research Institute for Islamic and Complementary
Medicine

Full name of responsible person

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Position

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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

Yes - There is 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

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data of the main outcome can be shared.

When the data will become available and for how long

starting 6 months after publication of article

To whom data/document is available

The data will be available for researchers in
complementary medicine.

Under which criteria data/document could be used

Requests will be reviewed.

From where data/document is obtainable

please mail to: dabaghian.f@iums.ac.ir

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

After reviewing the request, the answer will be provided
by email

Comments