

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Iranian medicine drug on increasing visual response to auditory stimuli in children with autism spectrum disorders; Double-blind clinical trial

Protocol summary

Study aim

To investigate the effect of Iranian medicine product on increasing the visual response to auditory stimuli in with autism

Design

This study is a randomized double-blind clinical trial study that will be conducted in parallel and with a ratio of 1:1. In this study, an experimental or interventional method will be used. In this way, we deeply examine the action and reactions between the factors that bring about change - the product of Iranian medicine - with the growth and expansion of the visual response of the autistic child. The case population is among the patients referred to Golhay Behesht Autism Spectrum Children's Rehabilitation Center in Qom who meet the inclusion criteria and do not use any other medication. Patients are randomly divided into two equal intervention and control groups.

Settings and conduct

The case population is among the patients referred to Golhay Behesht Autism Spectrum Children's Rehabilitation Center in Qom who meet the inclusion criteria and do not use any other medication. Patients are randomly divided into two equal intervention and control groups. Then the mothers of these children will be interviewed and consent to treatment with Iranian medicine products will be taken. Then, the temperament questionnaire is completed by interviewing the mothers and examining the children.

Participants/Inclusion and exclusion criteria

1) Children on the autism spectrum Center in Qom 2) Completion of informed 3) Do not take medicine 4) Age between 3 to 5 years

Intervention groups

Intervention group: 3 to 5 year old children with autism spectrum for whom traditional medicine products have been prescribed. Control group: Vedkan 3-5 years old

with autism spectrum for whom placebo was prescribed.

Main outcome variables

The rate of increasing the visual response to auditory stimulation by prescribing a traditional medicine product

General information

Reason for update

Acronym

درمان گیاهی اوتیسم

IRCT registration information

IRCT registration number: **IRCT20220628055306N1**

Registration date: **2022-08-31, 1401/06/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-31, 1401/06/09**

Update count: **0**

Registration date

2022-08-31, 1401/06/09

Registrant information

Name

Mohsen Dayani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3383 8303

Email address

najaf2@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Iranian medicine drug on increasing visual response to auditory stimuli in children with autism spectrum disorders; Double-blind clinical trial

Public title

The effect of Iranian medicine drug on increasing visual response to auditory stimuli in children with autism spectrum disorders

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having autism Parental consent

Exclusion criteria:

taking medication

Age

From **3 years** old to **5 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method will be used to assign people to intervention and control groups, and concealment will also be observed due to the use of this method. In this method, each person is assigned a unique code and it is pasted on the medicine packages, which will also help in the blinding process.

Blinding (investigator's opinion)

Double blinded

Blinding description

In conducting this study, the control group will be given a placebo and the center's therapists will be unaware of the allocation of the participants in the study to the intervention or control group. In this way, a unique code is assigned to each person and it is pasted on the medicine packages, and only the researcher is aware of the presence of each person in the Medakh group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Arak University of Medical Sciences

Street address

No.3, Dr Qarib Blvd, Dr Charmdooz Town

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2021-12-05, 1400/09/14

Ethics committee reference number

IR.ARAKMU.REC.1400.254

Health conditions studied**1****Description of health condition studied**

Treatment of autism with traditional medicine products

ICD-10 code

F84.0

ICD-10 code description

Childhood autism

Primary outcomes**1****Description**

Measuring the rate of visual response to multiple auditory stimuli

Timepoint

The second week, the fourth week, the sixth week, the eighth week

Method of measurement

Record the visual response to the auditory stimulus

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 3 to 5 year old children with autism spectrum disorder who are prescribed 5 cc of traditional medicine product three times a day for 8 weeks, which is a combination of basil plant, betel nut and green

cardamom fruit. Group members are evaluated every two weeks.

Category

Treatment - Drugs

2**Description**

Control group: 3 to 5 year old children with autism, for whom 5 cc of traditional medicine product which is a combination of basil plant and green cardamom fruit is given three times a day for 8 weeks and each time to be Group members are evaluated every two weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golhai Behesht Qom Rehabilitation Center for Autistic Children

Full name of responsible person

Mahdi Alaei

Street address

No.3, Alley 19, St.Amir kabir

City

Qom

Province

Ghous

Postal code

3713128569

Phone

+98 25 3650 1334

Fax

+98 25 3650 1335

Email

autism.qom97@gmail.com

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

Arak University of Medical Sciences

Full name of responsible person

Mehdi Salehi

Street address

No.3, Dr Gharib Blvd, Dr Charmdooz Town

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3313 6055

Fax

+98 86 3313 3147

Email

info@arakmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Mohsen Dayani

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

NO.3, Dr Gharib Blvd, Dr Charmdooz Town

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3313 6055

Email

najaf2@yahoo.com

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

Arak University of Medical Sciences

Full name of responsible person

Mohsen Dayani

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No. 3, Dr Gharib Blvd, Dr Charmdooz Town

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Markazi

Postal code

3819693345

Phone

+98 86 3313 6055

Email

najaf2@yahoo.com

Markazi

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Phone

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Email

najaf2@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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City

Arak

Province

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