

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Therapeutic effects of Thymex supplement syrup on autism symptoms and blood levels of inflammatory markers in autistic children

Protocol summary

Study aim

Determining the therapeutic effect of Thymex supplement syrup on autism symptoms and the level of blood inflammatory factors in autistic children

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 50 patients. The randomization method is random allocation. The randomization unit is an individual. The randomization tool is a sealed envelope.

Settings and conduct

For this study, we are considering Thymex 140 ml syrup. Each 100 ml of this syrup contains 660 mg of dry thyme plant extract. After obtaining the consent form from the parents of the patients, we have considered, for children aged 3 to 6 years, 3 times a day and 2.5 ml each time, and for children 6 to 10 years old, 3 times a day and 5 ml each time, for 1 month. The study is randomized, double-blind, that is, the participant, the clinical caregiver and the researcher do not know which patient will take the drug or placebo. Both groups receive standard autism treatment. Using the Gilliam questionnaire and measuring the level of inflammatory factors in the blood of the participants, the result of the intervention will be evaluated.

Participants/Inclusion and exclusion criteria

Children aged 3 to 10 with autism who do not have drug interactions due to the presence of a concurrent disease and the use of medication for its treatment, and who follow the study's consumption pattern and are willing to cooperate until the end of the study and are available.

Intervention groups

The intervention group includes children aged 3-10. Children aged 3-6 take 2.5ml of syrup 3 times a day. children aged 6-10 take 5ml of syrup 3 times a day. Both groups receive standard autism treatment.

Main outcome variables

Level of blood inflammatory factors and behavior of autism patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230314057720N1**

Registration date: **2023-07-12, 1402/04/21**

Registration timing: **prospective**

Last update: **2023-07-12, 1402/04/21**

Update count: **0**

Registration date

2023-07-12, 1402/04/21

Registrant information

Name

Rayehe Reisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3270 9027

Email address

reisirayehe@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of Thymex supplement syrup on autism symptoms and blood levels of inflammatory markers in autistic children

Public title

Effects of Thymex supplement syrup on autism symptoms in autistic children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Children with autism in the age range of 3 to 10 years

Exclusion criteria:

The presence of drug interactions
The presence of other diseases at the same time as autism
Non-acceptance of the patient in taking medication regularly
Non-cooperation of the patient in taking medication regularly

Age

From **3 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be gradually entered into the study in the treatment method and will be assigned to two intervention and control groups based on the random assignment method. For this purpose, we put the number of 50 cards with the letter A on 25 of them and the letter B on the other 25 in an envelope and randomly take out one card for each patient. The letter that comes out shows the group of the patient. Note that the doctor conducting the trial and the patient do not know about the syrups and B until the end of the study and the results, the study is double-blind. The randomization method is random allocation. The randomization unit is an individual. The randomization tool is a sealed envelope. The concealment is that cards A and B are placed in a sealed envelope and the allocator does not know the contents of the cards until the time of allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant in the study and the physician conducting the clinical trial and the researcher as well as the outcome assessor in this study are blinded. Medicine and placebo will be provided in the same packaging from the pharmaceutical company. Attributing the drug and placebo to A and B is the responsibility of the drug distributor.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Hajar Hospital, Parastar St, Shahrekord

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

۸۸۱۶۸۵۴۶۳۳

Approval date

2023-03-07, 1401/12/16

Ethics committee reference number

IR.SKUMS.MED.REC.1401.068

Health conditions studied

1

Description of health condition studied

Autism

ICD-10 code

F84.5

ICD-10 code description

Asperger's syndrome

Primary outcomes

1

Description

Stereotyped behaviors of children with autism

Timepoint

Evaluation of stereotyped behaviors of children with autism before the start of the intervention and 30 days after the start of taking Thymex supplement syrup

Method of measurement

Gilliam's Autism Questionnaire

2

Description

Communication in children with autism

Timepoint

Evaluation of communication in children with autism before the start of the intervention and 30 days after the start of Thymex supplement syrup

Method of measurement

Gilliam's Autism Questionnaire

3

Description

Social interactions in children with autism

Timepoint

Evaluation of social interactions in children with autism before the start of the intervention and 30 days after the start of taking Thymex supplement syrup

Method of measurement

Gilliam's Autism Questionnaire

4

Description

Developmental disorders in children with autism

Timepoint

Evaluation of developmental disorders in children with autism before the start of the intervention and 30 days after the start of taking Thymex supplement syrup

Method of measurement

Gilliam's Autism Questionnaire

5

Description

Interleukin-1 beta inflammatory factor levels

Timepoint

Measurement the level of the inflammatory factor interleukin-1 beta in children with autism before the intervention and 30 days after the start of Thymex supplement syrup

Method of measurement

Measurement the level of the inflammatory factor interleukin-1 beta using an ELISA kit

6

Description

TNF-alpha inflammatory factor level

Timepoint

Measurement the level of the inflammatory factor TNF-alpha in children with autism before the intervention and 30 days after the start of Thymex supplement syrup

Method of measurement

Measurement of TNF-alpha inflammatory factor level using ELISA kit

7

Description

Malondialdehyde level

Timepoint

Measurement the level of malondialdehyde in children with autism before the intervention and 30 days after the start of Thymex supplement syrup

Method of measurement

Measurement the level of malondialdehyde using an ELISA kit

8

Description

Total antioxidant capacity level

Timepoint

Measurement the level of total antioxidant capacity in children with autism before the start of the intervention and 30 days after the start of taking Thymex supplement syrup

Method of measurement

Measurement the level of total antioxidant capacity using an ELISA kit

9

Description

Nitric oxide levels

Timepoint

Measurement of nitric oxide levels in children with autism before the intervention and 30 days after the start of Thymex supplement syrup

Method of measurement

Measurement of nitric oxide level using ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: There are two types of Thymex syrup of Iran Darouk brand available in Iran, and for this study, we consider Thymex syrup of 140 ml Each 100 ml of Thymex Syrup contains 660 mg of Thymus vulgaris dry extract. The intervention group includes children with autism aged 3 to 10 years, children with autism 3 to 6 years old consume syrup 3 times a day and each time 2.5 ml, which is equivalent to a teaspoon, and children People with autism aged 6 to 10 years consume syrup 3 times a day and each time 5 ml, which is equivalent to two teaspoons. This group, at the same time as receiving Thymex syrup, receives the common treatment of autism, which depending on the patient can include drugs such as Risperidone, Aripiperazole or Methylphenidate. After 1 month of taking the drug according to the mentioned pattern, we will check the autistic behavior of the affected children by presenting a questionnaire based on the symptoms of autism to the parents of the affected. In order to investigate inflammatory markers and oxidative stress and to know the effect of the above drug on the levels of these markers, it is necessary to take a blood sample before the start of the study and a blood sample at the end of the 1-month study. The mentioned inflammatory factors are TNF-a and IL-1b, which are measured using an ELISA kit. The desired oxidative stress factors are malondialdehyde (MDA), antioxidant capacity (Total antioxidant capacity) and nitrite.

Category

Treatment - Drugs

2

Description

Control group: It includes children with autism between the ages of 3 and 10, who, like the intervention group, also receive common autism treatment, which, depending on the patient, can include drugs such as Risperidone, Aripiprazole, or Methylphenidate. At the same time, the members of the control group will receive the placebo, which is in the form of a syrup and made on the basis of ineffective medicinal substances, without the patient, researcher and project manager being informed. After 1 month of taking placebo according to the mentioned pattern, we will check the autistic behavior of the affected children by presenting a questionnaire based on the symptoms of autism to the parents of the affected. In order to investigate inflammatory markers and oxidative stress and to know the effect of the above drug on the levels of these markers, it is necessary to take a blood sample before the start of the study and a blood sample at the end of the 1-month study. The mentioned inflammatory factors are TNF-a and IL-1b, which are measured using an ELISA kit. The desired oxidative stress factors are malondialdehyde (MDA), antioxidant capacity (Total antioxidant capacity) and nitrite.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic

Full name of responsible person

Rayehe Reisi

Street address

In front of Finance Department, Shariati St,
Shahrekord

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Reisi

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Headquarters of Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Rayehe Reisi

Position

Medical Intern

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Email

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Medical Intern

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Hamedanian Flower and Plant Market, Hamedanian
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Person responsible for updating data

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Name of organization / entity

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Position

Medical Intern

Latest degree

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Other areas of specialty/work

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Email

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

En To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If there are conditions, all our data will be shared except personal information of people. The use of our data will only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data.

From where data/document is obtainable

En In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address reisirayehe@gmail.com or the contact number 00989370084728.

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

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments