# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 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

**City**
Shahrekord

**Province**
Chahar-Mahal-va-Bakhtiari

**Postal code**
8815713471

**Phone**
+98 38 3224 2696

**Email**
researchdecuty@skums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Shahre-kord University of Medical Sciences

**Full name of responsible person**
Elham Reisi

**Street address**
Headquarters of Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord

**City**
Shahrekord

**Province**
Chahar-Mahal-va-Bakhtiari

**Postal code**
۸۸۱۵۷۱۳۴۷۱

**Phone**
+98 38 3333 0061

**Email**
researchdecuty@skums.ac.ir

**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

**Street address**
Unit 103, Block J, Fadak Complex, In front of Hamedanian Flower and Plant Market, Hamedanian Street, Hasht Behesht East Street, Isfahan

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8157966571

**Phone**
+98 31 3270 9027

**Email**
reisirayehe@gmail.com

## Person responsible for scientific

## 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

**Street address**
Unit 103, Block J, Fadak Complex, In front of Hamedanian Flower and Plant Market, Hamedanian Street, Hasht Behesht East Street, Isfahan

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8157966571

**Phone**
+98 31 3270 9027

**Email**
reisirayehe@gmail.com

## Person responsible for updating data

**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

**Street address**
Unit 103, Block J, Fadak Complex, In front of Hamedanian Flower and Plant Market, Hamedanian Street, Hasht Behesht East Street, Isfahan

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8157966571

**Phone**
+98 31 3270 9027

**Email**
reisirayehe@gmail.com

## 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**