

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects of vitamin D and/or aquatic exercise on IL-1 β and IL-1RA serum levels and behavior of children with autism spectrum disorder

Protocol summary

Study aim

Evaluation of the effect of vitamin D and / or Aquatic exercise on serum levels of IL-1B, IL-1RA and the behavior of children with autism spectrum disorder

Design

A randomized controlled trial with parallel, double-blind, randomized groups of 80 children with autism spectrum disorder. Excel software rand function was used for randomization.

Settings and conduct

Execution of Blood sampling at Razi lab aquatic Exercise in the Behzisty pool of Rasht Vitamin D supplements based on the prescription of pediatric neurosurgeons Participants, Blood sampling, Laboratory scientist and Expert statistician, except the researcher and his aides, did not know the grouping of people in the research groups

Participants/Inclusion and exclusion criteria

Inclusion criteria included psychiatrist -diagnosed ASD (by Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition (DSM-V)), male gender, aged 6-8 years, no change in any medical, dietary or behavior treatment during the study, and parental informed consent.

Intervention groups

Aquatic Exercise group, vitamin D supplementation group, combination of Training and supplementation group and control group

Main outcome variables

Improving IL-1b, IL-1ra, vitamin D serum levels, stereotypic behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180503039517N5**

Registration date: **2020-09-26, 1399/07/05**

Registration timing: **retrospective**

Last update: **2020-09-26, 1399/07/05**

Update count: **0**

Registration date

2020-09-26, 1399/07/05

Registrant information

Name

Soleyman Ansari Kolachahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3375 2906

Email address

solomonansari@phd.iaurasht.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-18, 1399/05/28

Expected recruitment end date

2020-08-24, 1399/06/03

Actual recruitment start date

2020-08-18, 1399/05/28

Actual recruitment end date

2020-08-25, 1399/06/04

Trial completion date

2020-10-30, 1399/08/09

Scientific title

Effects of vitamin D and/or aquatic exercise on IL-1 β and IL-1RA serum levels and behavior of children with autism spectrum disorder

Public title

Effects of vitamin D and/or aquatic exercise on IL-1 β and IL-1RA serum levels and behavior of children with autism

spectrum disorder

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 psychiatrist –diagnosed ASD (by Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition (DSM-V)) Male gender aged 6-8 years no change in any medical, dietary or behavior treatment during the study parental informed consent
Exclusion criteria:
 Having comorbid disability or other Neuro-cognitive disorders receiving vitamin D supplements in the last 6 months

Age
From **6 years** old to **8 years** old

Gender
Male

Phase
N/A

Groups that have been masked

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

Sample size
 Target sample size: **80**
 Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
 Eighty children aged 6-8 years with autism spectrum disorder are selected by the available sampling method. Each person is assigned a number. It is then used to create groups randomly using the RAND function in Excel software. Eventually, 20 people will be replaced in each group (three experimental groups and one control group).

Blinding (investigator's opinion)
Double blinded

Blinding description
 In this study, blood samples and laboratory analysis experts are also unaware of the type of intervention and participating groups. Statistical analysts are not aware of the individuals and how the research is conducted.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Rasht Azad University Medical Sciences

Street address
Azad University of Rasht, Lakan Ave

City
Rasht

Province
Guilan

Postal code
4147654919

Approval date
2020-08-17, 1399/05/27

Ethics committee reference number
IR.IAU.RASHT.REC.1399.035

Health conditions studied

1

Description of health condition studied
Autism Spectrum Disorder

ICD-10 code
F84.0

ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
IL-1B serum levels

Timepoint
One week before starting and one week after terminating of intervention

Method of measurement
Dialclone human kit for IL-1B

2

Description
IL-1ra serum levels

Timepoint
One week before starting and one week after terminating of intervention

Method of measurement
ZellBio human kit for IL-1RA

3

Description
vitamin D serum level

Timepoint
One week before starting and one week after terminating of intervention

Method of measurement
Pars Azmoon human kit

4

Description
stereotypic behavior

Timepoint

One week before starting and one week after terminating of intervention

Method of measurement

Gars-2, stereotypic behaviors subscale

Secondary outcomes

empty

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

Intervention group: aquatic exercise (10 weeks, 2 session per week, 60 min training in pool). Each session includes a 5-minute warm-up, 15-minute orientation training, 20-minute basic swimming skills, 15-minute free swim and a 5-minute cool down.

Category

Lifestyle

2**Description**

Intervention group: vitamin D supplementation (for 10 weeks, once a week orally, along with having dinner, 500000 IU vitamin D). Vitamin D3 will be provided by Dana Pharmaceutical Company.

Category

Lifestyle

3**Description**

Intervention group: Combination of aquatic exercise and vitamin D supplementation. In this group, participants will receive both the intervention of the first group (aquatic exercise for 10 weeks) and the second group (vitamin D supplementation for 10 weeks) according to the same process mentioned above.

Category

Lifestyle

4**Description**

Control group: Participants in this group are asked to continue their normal and routine programs during the research period, as before. But refrain from participating in new diet, medicine and physical activity programs.

Category

Lifestyle

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

Guilan Autism Mehr Rain Association

Full name of responsible person

Mehdi Zahedi Kalashtari

Street address

second Fooladloo, Saffari Ave, Bisoton Ave

City

Rasht

Province

Guilan

Postal code

4193191933

Phone

+98 13 3351 3235

Email

Solomonansari@yahoo.com

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

Islamic Azad University

Full name of responsible person

Alireza Seydavi

Street address

Azad University of Rasht, Lakan Ave

City

Rasht

Province

Guilan

Postal code

۴۱۴۷۶۵۴۹۱۹

Phone

+98 13 3342 4073

Email

solomonansari@yahoo.com

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

No

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Fahimeh AdibSaber

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

Ansar Sport Club, 6th Ave, Keshavarz Ave, Valiasr Ave

City

Rasht

Province

Guilan

Postal code

4139617379

Phone

+98 13 3375 2906

Email

adibsaber@iaurasht.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Person responsible for updating data

Contact

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable