

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of aquatic exercise, Vitamin D supplementation and interactive of aquatic exercise and Vitamin D supplementation on serum level of IL-1B, IL-6, IL-10, IL-1ra, TNF-a, hs-CRP and Vitamin D in Children with Autism Spectrum Disorders

Protocol summary

Study aim

The effect of aquatic exercise, Vitamin D supplementation and interactive of aquatic exercise and Vitamin D supplementation on serum level of IL-1B, IL-6, IL-10, IL-1ra, TNF-a, hs-CRP and Vitamin D in Children with Autism Spectrum Disorders

Design

Randomised, factorial design and double blinded trial, with three intervention and one control group, Selection of available samples and randomised replacement in groups

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

sex (males) age (6 to 14) not having co-morbid disability parents satisfaction and presence

Intervention groups

aquatic exercise vitamin D supplementation interaction of aquatic exercise and vitamin D supplementation control

Main outcome variables

Improving IL-6, IL-10; IL-1b; IL-1ra, TNF-a; hs-CRP; vitamin D serum levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180503039517N1**

Registration date: **2018-07-13, 1397/04/22**

Registration timing: **retrospective**

Last update: **2018-07-13, 1397/04/22**

Update count: **0**

Registration date

2018-07-13, 1397/04/22

Registrant information

Name

Soleyman Ansari Kolachahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-03-11, 1396/12/20

Trial completion date

empty

Scientific title

The effect of aquatic exercise, Vitamin D supplementation and interactive of aquatic exercise and Vitamin D supplementation on serum level of IL-1B, IL-6,

IL-10, IL-1ra, TNF-a, hs-CRP and Vitamin D in Children with Autism Spectrum Disorders		Name of ethics committee Ethics committee of Rasht Azad University Medical Sciences	
Public title The effect of interactive of aquatic exercise and Vitamin D supplementation on some inflammatory Cytokines, hs-CRP and Vitamin D levels in Children with Autism Spectrum Disorders		Street address Azad University of Rasht, Lakan Ave	
Purpose Supportive		City Rasht	
Inclusion/Exclusion criteria Inclusion criteria: age (6 to 14) sex (male) not having co-morbid disability Exclusion criteria: Having more than two absence in the treatment sessions Receiving specialized treatment in addition to the usual treatments at their institution		Province Guilan	
Age From 6 years old to 14 years old		Postal code 4147654919	
Gender Male		Approval date 2017-09-19, 1396/06/28	
Phase N/A		Ethics committee reference number IR.IAU.RASHT.REC.1396.99	
Groups that have been masked • Participant • Outcome assessor • Data analyser		Health conditions studied 1 Description of health condition studied Autism Spectrum Disorder ICD-10 code F84.0 ICD-10 code description Childhood autism	
Sample size Target sample size: 40 Actual sample size reached: 40		Primary outcomes 1 Description IL-1B; IL-6; IL-10; IL-1ra; TNF-a; vitamin D, hs-CRP Timepoint One week before starting and on week after terminating of intervention Method of measurement Diaclone and ZellBio human kit	
Randomization (investigator's opinion) Randomized		Secondary outcomes empty	
Randomization description 40 children aged 6-14 years with autism spectrum disorder were selected using available sampling method. They will randomly divided into three intervention groups and one control group.		Intervention groups 1 Description Intervention group: Intervention group: aquatic exercise (10 weeks, 2 session per week, 60 min training in pool) Category Lifestyle	
Blinding (investigator's opinion) Double blinded		2 Description Intervention group: vitamin D supplementation (for 10 weeks, once a week orally, along with having dinner, 500000 IU vitamin D) Category Lifestyle	
Blinding description In this research, participants are unaware of the group assigned to themselves and other participants. A separate workout hour is considered for each intervention group. experts in laboratory analysis are also unaware of the type of intervention and the participating groups.			
Placebo Not used			
Assignment Factorial			
Other design features			
Secondary Ids empty			
Ethics committees 1 Ethics committee			

3

Description

Intervention group: composition of aquatic exercise and vitamin D supplementation (combining of intervention 1 and 2)

Category

Lifestyle

4

Description

Control group: no intervention, continuing past life style, not including in new activity

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan Autism Association

Full name of responsible person

Mehdi Zahedi Kalashtari

Street address

second Fooladloo, Saffari Ave, Bisoton Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zahra Hojjati

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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

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

Soleiman Ansari Kolachahi

Position

Phd student

Latest degree

Master

Other areas of specialty/work

Biochemistry

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable