

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effect of Swimming Training and Omega-3 Intake on Irisin and Body Composition in Obese Girls with Down Syndrome

Protocol summary

Study aim

The purpose of the present study was to omega-3 intake and eight weeks of swimming training on irisin and body composition obese girls with Down syndrome.

Design

Clinical trial with two groups with parallel, non-blind, randomized, randomized grouping were used.

Settings and conduct

Shahid Rezaei Brothers Pool, District 5 of Tehran, in addition to its daily activities, had 8 weeks of swimming training, which was 3 sessions per week and an average of 60 minutes per session. Swimming activities included a total of 10 minutes of warming up, 45 minutes of breast crawl swimming, and five minutes of cooling down.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Girls with Down Syndrome 3 to 15 years old, general practitioner's approval, daily activities, especially swimming. Exclusion criteria; Epilepsy, limb defects and Multi-disability

Intervention groups

Intervention Group 1 includes people with Down syndrome (9 people) who receive aerobic exercise intervention. Group 2 intervention includes people with Down syndrome (9 people) who receive omega-3 supplementation with aerobic exercise.

Main outcome variables

Irisin, body mass index, fat percentage, muscle percentage, cholesterol, triglycerides, Low Density Lipoprotein, High Density Lipoprotein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200506047324N1**

Registration date: **2020-06-05, 1399/03/16**

Registration timing: **retrospective**

Last update: **2020-06-05, 1399/03/16**

Update count: **0**

Registration date

2020-06-05, 1399/03/16

Registrant information

Name

ElhamAlsadat Zeinali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2288 8541

Email address

elhamz528@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Swimming Training and Omega-3 Intake on Irisin and Body Composition in Obese Girls with Down Syndrome

Public title

Effect of Swimming Training and Omega-3 Intake on Irisin and Body Composition in Obese Girls with Down Syndrome

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Girls with Down Syndrome, 3 to 15 years old, in the pool of Shahid Rezaei Brothers, Region 5 Tehran Public health approval based on a special questionnaire and general practitioner's approval In addition to daily activities, they have their own swimming exercises

Exclusion criteria:

People with epilepsy any physiological or metabolic abnormalities physical problems and obvious genetic abnormalities And there are several disabilities

Age

From **3 years** old to **15 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

Simplified Accidentalization Method Simple Accidental Methods Used Individual Accidental Hidden Sequence Sequence The use of opaque envelopes for division into two groups was a randomization tool using Rand Between software that divided individuals into two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad of Tehran University of Medical Sciences

Street address

Shariati St. - Khaghani St. - Islamic Azad University of Medical Sciences, Tehran - School of Medicine

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2019-09-01, 1398/06/10

Ethics committee reference number

IR.IAU.TMU.REC.1398.082

Health conditions studied

1

Description of health condition studied

Down Syndrome

ICD-10 code

Q90

ICD-10 code description

Down syndrome

Primary outcomes

1

Description

Irisin

Timepoint

Measure before using Omega 3 and training and after eight weeks of intervention

Method of measurement

ELISA method using ELISA Kit irisin kit with a picogram sensitivity of milliliters

2

Description

body weight

Timepoint

Measure before using Omega 3 and training and after eight weeks of intervention

Method of measurement

INBODY device

3

Description

fat percentage

Timepoint

Measure before using Omega 3 and training and after eight weeks of intervention

Method of measurement

INBODY device

4

Description

Muscle percentage

Timepoint

Measure before using Omega 3 and training and after eight weeks of intervention.

Method of measurement

INBODY device

5

Description

Cholesterol

Timepoint

Measure before using Omega 3 and training and after eight weeks of intervention
Method of measurement
Laboratory method

6

Description

Tri glyceride

Timepoint

Measure before using Omega 3 and training and after eight weeks of intervention

Method of measurement

Laboratory method

7

Description

Low Density Lipoprotein

Timepoint

Measure before using Omega 3 and training and after eight weeks of intervention

Method of measurement

Laboratory method

8

Description

High Density Lipoprotein

Timepoint

Measure before using Omega 3 and training and after eight weeks of intervention

Method of measurement

Laboratory method

9

Description

Height

Timepoint

Measure before using Omega 3 and training and after eight weeks of intervention

Method of measurement

centimeter

Secondary outcomes

empty

Intervention groups

1

Description

Swimming training, 8 weeks of swimming exercises, 3 sessions per week and an average of 60 minutes of swimming activity per session, which includes 10 minutes of warming up, 45 minutes of breast crawl swimming and five minutes of cooling. Warming up includes stretching exercises. It was out of the water and walking and warming up in the water. Cooling also includes playing in the water

Category

Other

2

Description

Intervention group: Swimming Training + Omega 3 Supplements 3. Get pre-workout supplements that have received 300 mg of Omega 3 capsules for 8 weeks and three times a week. Omega-3 capsules were purchased from the Ministry of Health's pharmaceutical company Alhawi.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

ElhamAlsadat Zeinali

Street address

Hafez Alley, at the end of Bani Hashem North Street, Resalat Highway

City

Tehran

Province

Tehran

Postal code

148- 16635

Phone

+98 21 2356 2000

Email

info@royaninstitute.org

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Meysam Mohammadnia

Street address

Afsariyeh Three Ways - Imam Reza Highway - 18 km - Shahr Ghiamdasht - End of Shahid Bahonar St. - Islamic Azad University, East Tehran Branch

City

Tehran

Province

Tehran

Postal code

1866113118

Phone

+98 21 3359 4950

Email

info@iauet.ac.ir

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

ElhamAlsadat Zeinali

Position

Master of Sports Nutrition

Latest degree

Master

Other areas of specialty/work

Others

Street address

No 37, West Kavian Alley, Jolfa Street

City

Tehran

Province

Tehran

Postal code

1541749415

Phone

+98 21 2284 3502

Email

ases.zeinali@yahoo.com

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

Islamic Azad University

Full name of responsible person

Shahin Riyahi Malayeri

Position

Assistant Professor of Exercise Physiology

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

Afsariyeh Three Ways - Imam Reza Highway - 18 km - Ghiamdasht City - End of Shahid Bahonar St. - Islamic Azad University, East Tehran Branch - Physical Education and Sports Sciences Department

City

Tehran

Province

Tehran

Postal code

1866113118

Phone

+98 21 3359 4950

Email

shahinriyahi@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Personal

Full name of responsible person

ElhamAlsadat Zeinali

Position

Master of Sports Nutrition

Latest degree

Master

Other areas of specialty/work

Others

Street address

No 37, West Kavin Alley, Jolfa Street

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Province

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Postal code

1541749415

Phone

+98 21 2284 3502

Email

ases.zeinali@yahoo.com

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

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

All data can be shared after people have not been identified

When the data will become available and for how long

After completing the research

To whom data/document is available

Sending data only to academic and scientific institutions

Under which criteria data/document could be used

Scientific research journals for judging articles

From where data/document is obtainable

Through the author in charge of Shahin Riahi Malayeri
shahinriahi @ yahoo.com

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

Sending a request to the desired email will be received
one week after sending

Comments