Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of zinc supplementation on education performance of children with Down syndrome in Tehran

Protocol summary

Summary

Zinc deficiency is one of the most important problems in society.This element is involved in the improvement of students cognitive activities and observed in the Former hippocampus of the brain and it deeply affect memory.with attention to The proven role of the zinc in the processes of cognitin and learning and Considering the fact that children with Down syndrome due to their disability that they suffer from, they are not able to take advantage of their ability in school. So The aim of this study was to evaluate the effect of zinc supplementation on the academic abilities of students with Down syndrome. The study included 44 male and female students with Down syndrome who are studying in special schools of Tehran. they will randomly selected. This study is double-blind. the case-study group will receive 20mg of Zinc gluconate daily, and control group will receive 20mg of placebo for 8 weeks daily .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405105670N9**
Registration date: **2015-09-07, 1394/06/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-07, 1394/06/16

Registrant information

Name

Ali Tarighat-Esfanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 300 5895

Email address

tarighata@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Private funding resource, or probably some resources allocate from Tabriz Medical Science university as a research project.

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zinc supplementation on education performance of children with Down syndrome in Tehran

Public title

Effect of zinc supplementation on education performance of children with Down syndrome in Tehran

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 7 to 15 years old children with Down syndrome who are studying in special schools in Tehran. Agreement to participate in the study: normal diet and mixed eating habits Criteria for excluding: receiving food supplements containing zinc since 6 months ago any history of disease(Hypothyroidism, epilepsy, heart disease,..) Any abnormal physiological and metabolic disease,Physical problems, organ defects, genetic abnormalities and visible disability

Age
From **7 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research and Technology Department of Tabriz University of Medical Sciences
Street address
3rd floor, Central Building #2, Tabriz University of Medical Sciences, Golgasht street,
City
Tabriz
Postal code
Approval date
2014-02-19, 1392/11/30
Ethics committee reference number
92230

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
Cognitive Actvities
Timepoint
Before intervention, 8 weeks after intervention
Method of measurement
Wechsler scale-4

2

Description
Educational performance
Timepoint
Before intervention, 8 weeks after intervention
Method of measurement
Wechsler scale-4

Secondary outcomes

1

Description
Hair Zinc level
Timepoint
Before intervention, 8 weeks after intervention
Method of measurement
ppm with flame atomic absorption spectrometry

2

Description
Food intake
Timepoint
Before intervention, 8 weeks after intervention
Method of measurement
24-hours recall for 3 sequential days

Intervention groups

1

Description
Participant will receive 20 ml syrup containing 20 mg of zinc daily, for 8 weeks in the form of zinc gluconate syrup receive. Supplements should be taken between meals
Category
Treatment - Drugs

2

Description
for 8 weeks, participants will receive 20 ml syrup containing 20 mg placebo (starch syrup) daily.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad Special school
Full name of responsible person

Zohreh Siyahpoush

Street address

Enqlab Eslami Educational complex, School station, Moalem Blvd, Yaft abad Street

City

Tehran

2

Recruitment center

Name of recruitment center

Ershad Special school

Full name of responsible person

Zohreh Siyahpoush

Street address

Nasim St, Patrice Lumumba St, Gisha St

City

Tehran

3

Recruitment center

Name of recruitment center

Zakerin Special school

Full name of responsible person

Zohreh Siyahpoush

Street address

Enqlab Eslami Educational complex, School station, Moalem Blvd, Yaft abad Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Private

Full name of responsible person

Zohreh Siyahpoush

Street address

No. 14, 4th Vahdat St, Shahed St, Payambar St, Ashrafi Esfahani St

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Private

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Nutrition Faculty

Full name of responsible person

Dr Ali Tarighat Esfanjani

Position

PHD/ Faculty member

Other areas of specialty/work

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Nutrition Faculty,Tabriz University of Medical Sciences, Abrasan St

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Phone

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Fax

Email

tarighat@zabarjad.ir

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty