Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy of vitamin E and alpha lipoic acid in decrease of oxidative stress in children with Down syndrome

Protocol summary

Summary

This study is a Randomized Controlled Trial to evaluate the effects of dietary alpha tocopherol and alpha lipoic acid supplements for reducing oxidative stress in children with Down syndrome. The study group consists of 105 children with DS aged 7-15 years. All children will select from Special Education Centers for Mentally Handicapped Children in different districts of Tehran, Iran.After selection of the centres parents will be invited to attend an information session. We will describe the procedures and details of the trial and will ask them to sign an informed consent form if they desir to participate their children in the trial. After that we allocate them to three groups randomly: alpha tocopherol (400 IU/d), ALA (100 mg/d) and placebo. The intervention period will take four months. Serum malondialdehyde (MDA) and urinary 8-hydroxydeoxyguanosine (8OHdG) will use as biomarkers of oxidative stress. These biomarkers will be measured on before and after intervention. For this reason we will take 5cc blood and 10 cc urine samples from children at baseline prior to supplementation and after 4 months of supplementation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102215111N1**
Registration date: **2013-10-30, 1392/08/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-10-30, 1392/08/08

Registrant information

Name

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Name of organization / entity

kermanshah university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Exceptional children research

Expected recruitment start date

2006-01-21, 1384/11/01

Expected recruitment end date

2006-05-22, 1385/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of vitamin E and alpha lipoic acid in decrease of oxidative stress in children with Down syndrome

Public title

The effect of dietary supplements of alpha lipoic acid and vitamin E on stress oxidative in children with Down syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:confirmation of regular trisomy 21 in children by cytogenetic analysis; not on any medication or vitamin supplementation therapy for six months before the start of intervention.

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: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran university of medical sciences
Street address
Tehran - Porsina St
City
Tehran
Postal code
Approval date
2005-12-27, 1384/10/06
Ethics committee reference number
132/8316

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
MDA
Timepoint
before intervention and after 4 months
Method of measurement
The determination of MDA levels will performed by method of Satho . In this method the reaction of MDA with Thiobarbituric acid (TBA) creates a complex which is determined spectrophotometrically.

2

Description
urinary 8-hydroxydeoxyguanosine (8OHdG)
Timepoint
before intervention and after 4 months
Method of measurement
8OHdG in urine samples will assessed using an enzyme-linked immunosorbent assay (ELISA) kit (8OHdG Quantitation, Cell Biolabs, Inc. San Diego).

Secondary outcomes

empty

Intervention groups

1

Description
In group 1 a capsule contained 400 IU alpha tocopherol will give to the children every day after dinner or lunch meal for 4 months.
Category
Treatment - Other

2

Description
In group 2 a capsule contained 100 mg alpha lipoic acidl will give to the children every day after dinner or lunch meal for 4 months.
Category
Treatment - Drugs

3

Description
In group 3 a capsule contained only vegetable oil as a placebotocopherol will give to the children every day after dinner or lunch meal for 4 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of exceptional children of Tehran
Full name of responsible person
Dr Azam Hoseinipor
Street address
Tehran Blv kashani
City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Exceptional Children Institute
Full name of responsible person
Dr. Kazem Dastjerdi
Street address
Gharani No 23
City
Tehran
Grant name
تحقیقاتی
Grant code / Reference number
0259
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Exceptional Children Institute
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
Name of organization / entity
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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