

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of lipoic acid on antioxidant factors, Th1/Th2 balance and clinical signs in multiple sclerosis patients

Protocol summary

Summary

The aim of this study is to investigate the effect of lipoic acid supplementation on serum level of lipoic acid, inflammation and antioxidant factors in multiple sclerosis patients. In this parallel randomized controlled trial, 60 men and women with multiple sclerosis will be recruited from center of multiple sclerosis of Sina hospital of Tehran university of medical science. Inclusion criteria are adults 18-51 years old, able to provide informed consent and diagnosed with relapsing remitting MS. Exclusion criteria are: MS exacerbation during of study, systemically administered corticosteroids during the study, pregnant or breast-feeding, other significant health problem (e.g. active coronary heart disease, liver disease, pulmonary disease, diabetes mellitus and other autoimmune disease) that might increase the risk of subject experiencing adverse events; consumption of vitamin, mineral and antioxidant supplement 30 days before study entry, any condition which would make the subject, in the opinion of the investigator, unsuitable for the study and compliance less than 70%. Prior to the study, the subjects will be required to complete 3-days 24-hour dietary recall. Diets will be analyzed for calorie and macronutrients and copper, iron, zinc and manganese content. Intervention group receives 1200 mg of lipoic acid as 2 capsules and other group receives 2 placebo capsules. Blood samples will be obtained after an overnight fast before and after the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812222602N2**

Registration date: **2010-03-13, 1388/12/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-03-13, 1388/12/22

Registrant information

Name

Shahryar Eghtesadi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Iran university of Medical Sciences

Expected recruitment start date

2010-09-02, 1389/06/11

Expected recruitment end date

2011-01-01, 1389/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lipoic acid on antioxidant factors, Th1/Th2 balance and clinical signs in multiple sclerosis patients

Public title

Effects of lipoic acid on inflammation and antioxidant factors in multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 18-51 years, able to provide informed consent and diagnosed with relapsing remitting MS. Exclusion criteria: MS exacerbation during the study, systemically administered corticosteroids during the study, pregnant or breast-feeding, other significant health problem (e.g. active coronary heart disease, liver disease, pulmonary disease, diabetes mellitus and other autoimmune disease) that might increase the risk of subject experiencing adverse events. Consumption of vitamin, mineral and antioxidant supplement 30 days before study entry, Any condition which would make the subject, in the opinion of the investigator, unsuitable for the study and compliance less than 70%.

Age

From **18 years** old to **51 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

School of Health, Iran University of Medical Sciences

Street address

Alvand Ave, Arjanteen Square

City

Tehran

Postal code

Approval date

2010-07-19, 1389/04/28

Ethics committee reference number

1421

Health conditions studied

1

Description of health condition studied

multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

decrease serum lipoic acid concentration

Timepoint

12 week

Method of measurement

HPLC

2

Description

decrease serum TNF-a concentration

Timepoint

12 week

Method of measurement

labratory kit

3

Description

decrease serum MDA concentration

Timepoint

12 week

Method of measurement

Spectrophotometry

4

Description

increase SOD

Timepoint

12 week

Method of measurement

Spectrophotometry

5

Description

increase glutathione peroxidase

Timepoint

12 week

Method of measurement

Spectrophotometry

6

Description

decrease serum ADA concentration

Timepoint

12 week

Method of measurement

ELISA

7

Description

decrease serum INF- γ concentration

Timepoint

12 week

Method of measurement

ELISA

8

Description

increase TGF-B

Timepoint

12 week

Method of measurement

ELISA

9

Description

increase IL-6

Timepoint

12 week

Method of measurement

ELISA

10

Description

increase IL-4

Timepoint

12 week

Method of measurement

ELISA

11

Description

decrease MMP-9

Timepoint

12 week

Method of measurement

ELISA

12

Description

decrease VCAM-1

Timepoint

12 week

Method of measurement

ELISA

13

Description

decrease ICAM-1

Timepoint

12 week

Method of measurement

ELISA

14

Description

TAC

Timepoint

12 week

Method of measurement

colorimetry

Secondary outcomes

1

Description

decrease EDSS

Timepoint

12 week

Method of measurement

observation

Intervention groups

1

Description

lipoic acid supplement (1200mg/day) for 90 days

Category

Treatment - Drugs

2

Description

control group: 2 capsuls including dietary fiber

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

MS research center of Sina hospital

Full name of responsible person

Mohamad Ali Sahraian

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Mohsen Asadi Lari

Street address

Hemmat highway

City

Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
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
School of Health, Iran University of Medical Sciences
Full name of responsible person
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Full Professor
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Person responsible for updating data

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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