

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8877 9118

###### Email address

egtesadi@iums.ac.ir

##### 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

ELYSA

## 7

### **Description**

decrease serum INF- $\gamma$  concentration

### **Timepoint**

12 week

### **Method of measurement**

ELYSA

## 8

### **Description**

increase TGF-B

### **Timepoint**

12 week

### **Method of measurement**

ELYSA

## 9

### **Description**

increase IL-6

### **Timepoint**

12 week

### **Method of measurement**

ELYSA

## 10

### **Description**

increase IL-4

### **Timepoint**

12 week

### **Method of measurement**

ELYSA

## 11

### **Description**

decrease MMP-9

### **Timepoint**

12 week

### **Method of measurement**

ELYSA

## 12

### **Description**

decrease VCAM-1

### **Timepoint**

12 week

### **Method of measurement**

ELYSA

## 13

### **Description**

decrease ICAM-1

### **Timepoint**

12 week

### **Method of measurement**

ELYSA

## 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**  
Dr. Shahriar Eghtesadi  
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Full Professor  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Other areas of specialty/work**  
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**Phone**  
**Fax**  
**Email**  
**Web page address**

## 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*