

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effect of alpha-lipoic acid supplementation on hs-CRP, interleukin-6, body weight and hypertention in male patients with chronic spinal cord injury

#### Protocol summary

##### Summary

object:The effect of alpha-lipoic acid supplementation on hs-CRP, interleukin-6, body weight and hypertention in male patients with spinal cord injury This is a randomized, double-blind, placebo-controlled, single centerstudy in the 2-3 phase of clinical trial. inclusion criteria: male; spinal cord injury for at least a year and the maximum is 10 years past the onset of disease; BMI $\geq$ 18.5; Complete spinal cord injury (lack of motor function below the lesion); age between 30-50 years; informed consent; Lack of specific diseases and malignancies such as liver disease; kidney disease and cancer; Exclusion criteria: not wanting Collaboration; Failure to follow the program of receiving supplements (less than 80%); changes in food pattern ; certain diseases and malignancies during study; Use of antioxidant supplements of at least one month prior to study entry and during study 70 Eligible patients divided into two groups, intervention and placebo and take 600 mg Alpha Lipoic Acid and placebo for 12 weeks respectively. we expect changes in levels of hs-CRP, IL-6, weight, blood pressure, blood sugar and dietary intake in the intervention group than baseline and the placebo group before and after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201106122602N6**

Registration date: **2012-05-06, 1391/02/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-05-06, 1391/02/17

#### 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

Tehran University of Medical Sciences

#### Expected recruitment start date

2012-05-09, 1391/02/20

#### Expected recruitment end date

2012-10-21, 1391/07/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of alpha-lipoic acid supplementation on hs-CRP, interleukin-6, body weight and hypertention in male patients with chronic spinal cord injury

#### Public title

The effect of alpha-lipoic acid supplementation on hs-CRP, interleukin-6, body weight and hypertention in male patients with chronic spinal cord injury

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

inclusion criteria: male; spinal cord injury for at least a year and the maximum is 10 years past the onset of disease; BMI $\geq$ 18.5; Complete spinal cord injury (lack of motor function below the lesion); age between 30-50 years; informed consent; Lack of specific diseases and malignancies such as liver disease; kidney disease and cancer; Exclusion criteria: no Collaboration; Failure to follow the program of receiving supplements (less than 80%); changes in food pattern ; certain diseases and malignancies during study; Use of antioxidant supplements of at least one month prior to study entry and during study

**Age**

From **30 years** old to **50 years** old

**Gender**

Male

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **70**

**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**

Sixth Floor,Central Organization of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd

**City**

Tehran

**Postal code****Approval date**

2012-04-15, 1391/01/27

**Ethics committee reference number**

2623/130/90/3

**Health conditions studied****1****Description of health condition studied**

Chronic spinal cord injury

**ICD-10 code**

TO9.3

**ICD-10 code description**

Injury of spinal cord, level unspecified

**Primary outcomes****1****Description**

hs-CRP

**Timepoint**

Before and after intervention

**Method of measurement**

ELISA

**2****Description**

IL-6

**Timepoint**

Before and after intervention

**Method of measurement**

ELISA

**3****Description**

weight

**Timepoint**

Before and after intervention

**Method of measurement**

Wheelchair scales

**4****Description**

Waist circumference

**Timepoint**

Before and after intervention

**Method of measurement**

Meter

**5****Description**

Systolic blood pressure

**Timepoint**

Before and after intervention

**Method of measurement**

Mercury barometer

**6****Description**

Diastolic blood pressure

**Timepoint**

Before and after intervention

**Method of measurement**

Mercury barometer

## 7

### **Description**

FBS

### **Timepoint**

Before and after intervention

### **Method of measurement**

Colorimetric autoanalyzer

## 8

### **Description**

Energy intake

### **Timepoint**

Before and after intervention

### **Method of measurement**

recall

## 9

### **Description**

Carbohydrates intake

### **Timepoint**

Before and after intervention

### **Method of measurement**

recall

## 10

### **Description**

Protein intake

### **Timepoint**

Before and after intervention

### **Method of measurement**

recall

## 11

### **Description**

fat intake

### **Timepoint**

Before and after intervention

### **Method of measurement**

recall

## 12

### **Description**

BMI

### **Timepoint**

Before and after intervention

### **Method of measurement**

mathematics

## **Secondary outcomes**

## 1

### **Description**

vitamin C

### **Timepoint**

before and after intervention

### **Method of measurement**

recall

## 2

### **Description**

vitamin E

### **Timepoint**

before and after intervention

### **Method of measurement**

recall

## **Intervention groups**

## 1

### **Description**

alpha- lipoic acid, capsule 600 mg, once a day for 12 weeks

### **Category**

Treatment - Drugs

## 2

### **Description**

placebo, 600 mg capsule, once a day for 12 weeks

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Spinal cord injuries clinic, Emam khomeini hospital

#### **Full name of responsible person**

Dr Hooshang Saberi

#### **Street address**

Emam khomeini hospital- keshavarz Blvd

#### **City**

Tehran

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Tehran University of Medical Sciences

#### **Full name of responsible person**

Dr. Masoud Yunesian

#### **Street address**

Research section-Tehran University of Medical Sciences- Ghods st- Keshavarz Blvd- Tehran

#### **City**

Tehran

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Tehran 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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Vida Mohammadi  
**Position**  
MA student of Nutrition sciences  
**Other areas of specialty/work**  
**Street address**  
Department of Nutrition- Health school- Tehran  
University of Medical Sciences-Alvand st.- Argentine  
Square- Tehran  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 8877 9118  
**Fax**  
**Email**  
mohammadi\_vida@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr. Shahryar Eghtesadi  
**Position**  
PhD of Nutrition sciences  
**Other areas of specialty/work**  
**Street address**  
Department of Nutrition- Health school- Tehran

University of Medical Sciences-Alvand st.- Argentine  
Square- Tehran  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 8877 9118  
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**Email**  
egtesadi@yahoo.com  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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Vida Mohammadi  
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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*