Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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>=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>=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/د

Health conditions studied

1

Description of health condition studied
Chronic spinal cord injery

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, 6oo 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

Fax

Email

egtesadi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

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Department of Nutrition- Health school- Tehran University of Medical Sciences-Alvand st.- Argentine Square- Tehran

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mohamadi_vida@yahoo.com

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