

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effects of Astaxanthin on the recovery of patients with complete spinal cord injury: A clinical trial study

Protocol summary

Study aim

Therapeutic effects of astaxanthin on the improvement of patients with complete spinal cord injury

Design

A randomized, double-blinded, placebo-controlled clinical trial (Phases 1 and 2) with a parallel group design of 40 patients with SCI followed for one year.

Settings and conduct

Patients with complete SCI admitted to Shohadaye - Tajrish hospital take one 12 mg soft capsule of astaxanthin or placebo daily for 2 months. The therapeutic effect of astaxanthin on functional recovery, pain, spasticity, muscle activity, the extent of tissue damage, and serum level of inflammatory factors including TNF- α , TGF β , IL-6, urodynamics, liver enzymes, and CBC in patients is investigated for a year. Blood samples(taken at 15 time -points(zero, 15, 30, 45, and 60 days after treatment and then at 3, 6, and 12 months of study). MRI will be performed before and after drug therapy on 3, 6, and 12 months after the beginning of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients with complete spinal paralysis at the thoracic level - Patients in the acute and sub-acute stages of SCI - Patients between 18 -60 years old. Exclusion criteria: - Patients with a medical history of MI and CAD, chronic infections and CKD, pregnancy, concurrent infections, or GI bleeding. - Multiple-level spinal injuries - Spinal instability of vertebra - Traumatic brain injury associated with SCI - Isolated radiculopathy - Skeletal fracture or muscle atrophy - Drug abuse - Coexistence of psychiatric disorders

Intervention groups

Treatment group: receive astaxanthin Control group: receive placebo

Main outcome variables

Neurological disorders, the extent of the injury area, muscle electrical activity, serum level of TNF- α , TGF β , IL-6, pain, spasticity, liver enzymes, and CBC Diff

changes

General information

Reason for update

Acronym

AST&SCI

IRCT registration information

IRCT registration number: **IRCT20231024059828N1**

Registration date: **2023-11-11, 1402/08/20**

Registration timing: **prospective**

Last update: **2023-11-11, 1402/08/20**

Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

MASOUMEH JORJANI

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-07-20, 1403/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of Astaxanthin on the recovery of patients with complete spinal cord injury: A clinical trial study

Public title

Astaxanthin in spinal cord injury

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with spinal cord injury at the thoracic level who have complete spinal paralysis. Patients in the acute (one week after the injury) and sub-acute (1 to 8 weeks) stages admitted to Shohada Tajrish Hospital. This study is in patients aged 18-60 years old.

Exclusion criteria:

Patients with past medical history of myocardial infarction and coronary artery disease, chronic infections and CKD, pregnancy, concurrent infections or gastrointestinal bleeding. Multiple level spinal injuries Spinal instability of vertebra Traumatic brain injury associated with SCI Isolated radiculopathy Skeletal fracture or muscle atrophy Drug abuse Coexistence of psychiatric disorders

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **8**

Patients with thoracic spinal cord injury

Randomization (investigator's opinion)

Randomized

Randomization description

A straightforward method of randomization using a table of random numbers involves assigning even numbers to intervention A and odd numbers to intervention B, as preferred by the researcher

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients who have inclusion criteria, sign the informed consent form, and then they are assigned to receive a random code for the treatment including a placebo or drug. Patients are randomly assigned to two groups, A and B. Bottles of drug containing 60 soft gel capsules are labeled A or B as well. Only the principal investigator, not the clinician, care provider, or patient, knows about the

content of each bottle (drug or placebo). The patients randomly receive a bottle A or B according to the label. In order to follow up on patients, a detailed schedule of examinations and cross-sectional sampling of patients is prepared. During the follow-up period, two members of the research team will contact patients to remind them for further medical exams and sample collection.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Public Health and Neuroscience Research Center-Shahid Behesh

Street address

Dept. of Pharmacology & Neurobiology Res. Cent, School of Medicine, Shahid Beheshti Univ. Med. Sci., koodakyar St., Daneshjoo Blvd., Velenjak

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Approval date

2023-10-17, 1402/07/25

Ethics committee reference number

IR.SBMU.PHNS.REC.1402.074

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

Spinal Cord Injury

ICD-10 code

T09.3

ICD-10 code description

Injury of spinal cord, level unspecified

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

Neuropathic pain

Timepoint

at the beginning of the study and during treatments at the 2, 4, 6 and 8th week, then at the 3rd, 6th, and 12th months

Method of measurement

Questionnaire Neuropathique Douleur 4 scale, Visual Analog Scale

2**Description**

spasticity

Timepoint

Before starting the study, the first, second and eighth weeks and in the 3rd, 6th and 12th months

Method of measurement

Electromyography (EMG)

3**Description**

Neurological disorder (sensory and motor dysfunction)

Timepoint

at the beginning of the study and during treatments at the 2, 4, 6 and 8th week, then at the 3rd, 6th, and 12th months

Method of measurement

Questionnaire: American Spinal Injury Association (ASIA), Spinal Cord Independence Measure (SCIM)

4**Description**

Serum level of inflammatory factors TNF- α , IL-6 and TGF β

Timepoint

Before starting the study, the first, second and eighth weeks and in the 3rd, 6th and 12th months

Method of measurement

ELISA test

5**Description**

Examination of liver enzymes Alkaline Phosphatase (ALP), serum glutamic-pyruvic transaminase (SGPT) and serum glutamic-oxaloacetic transaminase (SGOT)

Timepoint

at the beginning of the study and during treatments at the 2, 4, 6 and 8th week, then at the 3rd, 6th, and 12th months

Method of measurement

ELISA test

6**Description**

Complete blood count (HB, RBC, WBC, PLT)

Timepoint

at the beginning of the study and during treatments at the 2, 4, 6 and 8th week, then at the 3rd, 6th, and 12th months

Method of measurement

spectrophotometer

7**Description**

The size of the injured area

Timepoint

at the beginning of the study, and then at the 3rd, 6th and 12th months

Method of measurement

Magnetic resonance imaging (MRI)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients receive a 12 mg astaxanthin soft capsule (manufactured by Cheeky Nutrition, UK) orally for two months. Astaxanthin is a beta carotenoid that is extracted from micro algae Haematococcus pluvialis. It had high antioxidant properties and is used as a supplement to strengthen the immune system.

Category

Treatment - Drugs

2**Description**

Control group: The placebo group receive one soft capsule daily with excipients similar to astaxanthin and without the active ingredient (manufactured by Sana Pharmed Iran) orally for two months.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohadaye Tajrish Hospital

Full name of responsible person

Saeed Oraee Yazdani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Deputy of research and technology- Dr. Afshin Zarghi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Province

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the results will be published as an article in an international journal

When the data will become available and for how long

The start of the access period after the publication of the article

To whom data/document is available

After the publication of the article, all people can access the results of the study

Under which criteria data/document could be used

With the permission of the Principal investigators

From where data/document is obtainable

Principal investigators - 1-Masoume Jarjani 2-Alireza Zali

What processes are involved for a request to access data/document

Contact the principal investigators

Comments

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