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، ،TGFβ، 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، ،TGFβ، 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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Iran (Islamic Republic of)

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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 (AISA), Spinal Cord Independence Measure (SCIM)

4

Description
Serum level of inflammatory factors TNF-α , IL-6and TGFβ
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
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Sponsors / Funding sources

1

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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

Person responsible for general inquiries

Contact
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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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