

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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- $\alpha$ , TGF $\beta$ , 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- $\alpha$ , TGF $\beta$ , 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 9969

##### Email address

msjorjani@sbmu.ac.ir

##### 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**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- $\alpha$ , IL-6 and TGF $\beta$

**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

**Street address**

Tehran Province, Tehran, Shahr-dari St, Shohadaye Tajrish Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2271 8000

**Email**

pr-shohada@sbmu.ac.ir

**Web page address**

<https://shmc.sbmu.ac.ir/>

## 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

**Street address**

7th Floor, Bldg No.2 SBMU, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Phone**

+98 21 2242 2402

**Email**

info@sbmu.ac.ir

**Web page address**

<https://sbmu.ac.ir/>

**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**

Tehran

**Postal code**

1983969411

**Phone**

+98 21 2243 9969

**Fax****Email**

msjorjani@sbmu.ac.ir

**Web page address**

<https://pharmacology.sbmu.ac.ir>

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza Zali

**Position**

Academic Prof.

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

Dept. of Neurosurgery, Shohadaye Tajrish Hospital, Shahrdari St,

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2271 8000

**Fax****Email**

dr\_alirezazali@yahoo.com

**Web page address**

<https://fnrc.sbmu.ac.ir>

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Masoumeh Jorjani

**Position**

Academic Prof.

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacology

**Street address**

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

**City**

Tehran

## Person responsible for updating data

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Masoumeh Jorjani

**Position**

Academic Prof.

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Phone**

+98 21 2243 9969

**Fax****Email**

msjorjani@sbmu.ac.ir

**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**

-