Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the sodium selenium administration on the level of inflammatory factors, oxidative stress and functional and cognitive scores in acute ischemic stroke patients

Protocol summary

Study aim
Evaluation of the sodium selenium administration on the level of inflammatory, oxidative and functional and cognitive scores in patients with cerebral ischemic stroke

Design
Two arms parallel group randomized trial with blinded outcome assessment

Settings and conduct
This study will be carried out after obtaining permission from the ethics committee of Shahid Beheshti University of Medical Sciences and consent of the head of neurology department of Loghman Hakim Hospital as a clinical trial on patients with acute stroke. They will be randomly divided into two groups. 1. Selenium treatment group with a dose of 2000 µg after admission and then 1000 µg for 5 days. 2. Placebo group, receive saline initially at a dose of 40cc and then 20cc for 5 days. The blood sample and NIHSS, MRS, MMSE will be taken from patients at the time of entry and end of day 30.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with acute stroke Exclusion criteria: Receiving antioxidants constantly (such as vitamin C and E) Receiving anti-inflammatory drugs constantly(steroids, nonsteroidal anti-inflammatory) Suffered from HIV and neurodegenerative diseases (e.g. Alzheimer's, Parkinson's, amyotrophic lateral sclerosis, multiple sclerosis) Systemic diseases such as Diabetes Mellitus, Renal Failure, Malignant Melanoma, Uremia, Myopathy, and Congestive Heart Failure Loss of consciousness level due to any reason except stroke (such as shock, alcohol consumption or intoxication)

Intervention groups
Acute ischemic stroke patients are divided into two groups of Selenium and placebo treatment, which is similar to the drug.

Main outcome variables
Level of tumor necrosis factor alpha(TNF-α), superoxide dismutase (SOD), glutathione peroxidase(Gpx)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170104031773N3**
Registration date: **2019-06-09, 1398/03/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-09, 1398/03/19**
Update count: **0**

Registration date
2019-06-09, 1398/03/19

Registrant information

Name
Leila Simani

Name of organization / entity
Shahid Beheshti Medical University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the sodium selenium administration on the level of inflammatory factors, oxidative stress and functional and cognitive scores in acute ischemic stroke patients

Public title

Effect of sodium selenium administration on functional and cognitive scores in ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with acute stroke

Exclusion criteria:

Receiving antioxidants constantly (such as vitamin C and E) Receiving anti-inflammatory drugs constantly(steroids, nonsteroidal anti-inflammatory) Suffered from HIV and neurodegenerative diseases (e.g. Alzheimer's, Parkinson's, amyotrophic lateral sclerosis, multiple sclerosis) Systemic diseases such as Diabetes Mellitus, Renal Failure, Malignant Melanoma, Uremia,Myopathy, and Congestive Heart Failure Loss of consciousness level due to any reason except stroke (such as shock, alcohol consumption or intoxication)

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block random sampling will be used. In the present study, there are two groups (intervention group and control group). Therefore, four blocks will be used. According to the sample size (60 people in total, 30 in each group), 15 blocks of four will be considered. The random allocation of individuals to the groups under study will be done as follows: First, there are 15 envelopes containing four cards with ABCD Latin letters, the letters A and B = the intervention group, the letters C and D = will be considered as the control group. According to the inclusion criteria, the patients were asked to choose one of the 15 seals envelopes randomly and select a random card from the inside, which is based on the card's adhesive that determines the allocation of the individual to either of the two study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants and the individual who evaluates the outcome are unaware of the allocation of drugs and placebo. Before starting a medication, it will be explained to each patient that ،they will be treated with an intravenous drug. But the patients do not know what medicine they have received. The physician is a neurological assistant who is not involved in the study design, interventions, and specific objectives under study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak St’ Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-02-03, 1397/11/14

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1214

Health conditions studied

1

Description of health condition studied

Ischemic stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

The level of tumor necrosis factor alpha(TNF-α)

Timepoint

At the beginning of the study (before the intervention), 1 month after the start of taking sodium selenite

Method of measurement

Blood sample

2

Description
The level of superoxide dismutase (SOD)
Timepoint
At the beginning of the study (before the intervention), 1 month after the start of taking sodium selenite
Method of measurement
Blood Sample

3

Description
The level of glutathione peroxidase(GPx)
Timepoint
At the beginning of the study (before the intervention), 1 month after the start of taking sodium selenite
Method of measurement
Blood Sample

Secondary outcomes

1

Description
Motor function and verbal
Timepoint
At the beginning of the study (before the intervention), 1 month after the start of taking sodium selenite
Method of measurement
National Institues of Health Stroke Scale Questionnaire

2

Description
Cognitive performance
Timepoint
At the beginning of the study (before the intervention), 1 month after the start of taking sodium selenite
Method of measurement
Mini Mental State Examination Questionnaire

3

Description
Degree of disability
Timepoint
At the beginning of the study (before the intervention), 1 month after the start of taking sodium selenite
Method of measurement
Modified Rankin Scale Questionnaire

Intervention groups

1

Description
500µg Selenase injection vial contains 1.67mg sodium selenite pentahydrate (German biosyn company), receiving a dose of 2000 µg after admission and then 1000 µg for 5 days.
Category
Treatment - Drugs

2

Description
Placebo group, receive saline initially at a dose of 40cc and then 20cc for 5 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Leila Simani
Street address
Loghman Hakim Hospital, Makhsoos St., Lashkar CUV
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zaerghi
Street address
Research and Technology Center, Shahid Beheshti University of Medical Sciences,Student Blvd, Velenjak
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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

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leila Simani

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

Neuroscience

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Part of the data is the main consequence of the study

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia and industry

Under which criteria data/document could be used

Therapeutic use

From where data/document is obtainable

Leila Simani l.simani90@sbmu.ac.ir

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

After submitting the request and checking the available items,The data is obtained

Comments