Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating of vitamin D administration on the level of inflammatory factors and functional and cognitive scores in patients with cerebral ischemic stroke

Protocol summary

Study aim

In order to achieve more effective therapeutic protocols against ischemic events in the brain, the main aim of this study was to investigate the relationship between blood levels of vitamin D changes and their simultaneous administration with stroke injuries.

Design

A clinical trial with a control group and two treatment groups with two types of vitamin D administration, with parallel, double blind, randomized groups

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.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with vitamin D deficiency (less than 20 ng per ml) Patients with moderate acute stroke based on the NIHSS scoring system Exclusion criteria: The serum level of vitamin D is above 20 ng per ml Receive antioxidants (such as vitamins C and E) continuously Receive continuous anti-inflammatory drugs (steroids-NSAIDs) AIDS and neurodegenerative diseases (such as Alzheimer's, Parkinson's, ALS, MS) Systemic diseases like, Diabetes Mellitus, Kidney Failure, Malignant Melanoma, Uremia, Liver Cirrhosis and Chronic Myocardial Infarction, Myopathy Change in mental status with unknown etiology

Intervention groups

The intervention consists of three groups.The first group receives oral vitamin D,The second group receives vitamin D injection,The third group is the control group, which only measures vitamin D levels and recovery rates without receiving vitamin D.

Main outcome variables

level of Vitamine D; TNF-a; IL-6; NIHSS; MRS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170104031773N2**
Registration date: **2019-03-08, 1397/12/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-08, 1397/12/17**
Update count: **0**

Registration date

2019-03-08, 1397/12/17

Registrant information

Name

Leila Simani

Name of organization / entity

Shahid Beheshti Medical University

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating of vitamin D administration on the level of inflammatory factors and functional and cognitive scores in patients with cerebral ischemic stroke

Public title
Vitamin D in ischemic stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with vitamin D deficiency (less than 20 ng per ml) Patients with moderate acute stroke based on the NIHSS scoring system
Exclusion criteria:
The serum level of vitamin D is above 20 ng per ml Receive antioxidants (such as vitamins C and E) continuously Receive continuous anti-inflammatory drugs (steroids-NSAIDs) AIDS and neurodegenerative diseases (such as Alzheimer's, Parkinson's, ALS, MS Systemic diseases like, Diabetes Mellitus, Kidney Failure, Malignant Melanoma, Uremia, Liver Cirrhosis and Chronic Myocardial Infarction, Myopathy Change in mental status with unknown etiology
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, Random numbers table
Blinding (investigator's opinion)
Double blinded
Blinding description
participants, Clinical care and the individual who evaluates the outcome
Placebo
Not 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
2018-11-12, 1397/08/21
Ethics committee reference number
IR.SBMU.RETECH.REC.1397.642

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
Timepoint
At the beginning of the study (before the intervention), 1 month after the start of taking vitamin D
Method of measurement
Blood sample

2

Description
The level of Interleukin 6
Timepoint
At the beginning of the study (before the intervention), 1 month after the start of taking vitamin D
Method of measurement
Blood sample

3

Description
the level of vitamin D
Timepoint
At the beginning of the study (before the intervention), 1 month after the start of taking vitamin D
Method of measurement
Blood Sample

Secondary outcomes

1

Description
National Institues of Health Stroke Scale Measurement
Timepoint
At the beginning of the study (before the intervention), 1 and 3 months after the start of taking vitamin D
Method of measurement
National Institues of Health Stroke Scale Questionnaire

2

Description
Measuring Mini Mental State Examination
Timepoint
At the beginning of the study (before the intervention), 1 and 3 months after the start of taking vitamin D
Method of measurement
Mini Mental State Examination Questionnaire

3

Description
Measuring Modified Rankin Scale
Timepoint
At the beginning of the study (before the intervention), 1 and 3 months after the start of taking vitamin D
Method of measurement
Modified Rankin Scale Questionnaire

Intervention groups

1

Description
First intervention group: Injection of two vitamins D 3 with a dose of 300,000 units. The first dose is taken after confirmation vitamin D deficiency at the beginning of the disease, and the second dose is one month after the first dose. It used Intramuscular and the drug belongs to the Osweh Pharmaceutical Company.
Category
Treatment - Drugs

2

Description
Second intervention group: The patient will receive 6 pearls of vitamin D3 orally at a dose of 50,000 units.The first dose is taken after confirmation of vitamin D deficiency in the patient and next doses are taken weekly after the first dose. The drug belongs to Dana Pharmaceutical Company.
Category
Treatment - Drugs

3

Description
Control group: In this group, the drug is not given to the patient and only the level of vitamin D is measured at the beginning and one month later.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
لیلا سی منی
Street address
Loghman Hakim Hospital, Makhsoos St., Lashkar CUV.
City
Tehran
Province
Tehran
Postal code
1333631151
Phone
+98 21 5102 5296
Email
l.simani90@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
لیلا سی منی
Street address
Velenjak St’ Shahid Chamran Highway
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Postal code
1985717443
Phone
+98 21 5102 5182
Email
l.simani90@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

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leila Simani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Neuroscience

Street address

Loghman Hakim Hospital, Makhsoos St., Lashkar CUV.

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Person responsible for scientific 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 updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leila Simani

Position

Consultant

Latest degree

Ph.D.

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 which 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