# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

24 Jun 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**

+98 21 5102 5582

**Email address**

l.simani90@sbmu.ac.ir

**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
**City**
Tehran
**Province**
Tehran
**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.

**City**

Tehran

**Province**

Tehran

**Postal code**

1333631151

**Phone**

+98 21 5102 5182

**Email**

l.simani90@sbmu.ac.ir

## 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

**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

## 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

**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

## 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**