

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Effect of high dose vitamin D on serum Neuron Specific Enolase (NSE) level as a marker of neuronal damage in patients with ischemic stroke

Protocol summary

Study aim

Evaluating the effect of high dose vitamin D on Neuron Specific Enolase blood level as a neuronal damage biomarker

Design

Two arms open-label parallel-group randomized (by RAND function of Excel software) clinical trial including two groups of intervention and control, on ∞ patients

Settings and conduct

In this study, 40 patients with moderate ischemic stroke (NIHSS 5-15) will be recruited from the neurology clinics of Imam Hossein Hospital, Tehran. Patients will be randomly assigned into groups A (intervention group) and B (control group). Subjects in group A will receive a single dose of 600000 units of vitamin D by intramuscular injection besides standard treatment. Five milliliters of the blood sample will be gathered from each subject before the entrance to the study and 3 days after recruitment in order to measure neuron-specific enolase level. To evaluate the clinical impact of the intervention, NIHSS will be measured daily until the patient is hospitalized and Barthel index will be measured 3 months after stroke

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 16 to 75 years suffered from moderate ischemic stroke (NIHSS 5-15) Exclusion criteria: Patients who had myocardial infarction 30 days before the stroke and vitamin D blood level more than 30ng/ml

Intervention groups

Intervention group: Subjects who will receive a single dose of 600,000 units of vitamin D by IM injection pulse standard care Control group: Patients who will receive standard care

Main outcome variables

Changes of neuron-specific enolase between two arms of the study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120703010178N24**

Registration date: **2021-04-09, 1400/01/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-09, 1400/01/20**

Update count: **0**

Registration date

2021-04-09, 1400/01/20

Registrant information

Name

Mohammad Sistanizad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0087

Email address

sistanizadm@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high dose vitamin D on serum Neuron Specific Enolase (NSE) level as a marker of neuronal damage in patients with ischemic stroke

Public title

Effect of high dose vitamin D in patients with ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Ischemic Stroke Patients over 16

Exclusion criteria:

Myocardial infarction in past 30 days Vitamin D level more than 30ng/ml

Age

From **16 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Blood sample

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to intervention and control arms of the study by simple randomization method using a series of unique random numbers generated by the RAND function in Excel software as below: 1- In column A, numbers 1-30 and 31 to 60 categorized as control and intervention, respectively. 2- In column B, the RAND function was run. 3- Columns A and B were copied and the values pasted in another sheet. 4- The sheet was sorted based on column B. So, the subjects in column A (control and intervention) were distributed randomly based on the random numbers generated in column B. 5- Numbers 1 to 60 were allocated in column C as subject number. Column B was deleted

Blinding (investigator's opinion)

Not blinded

Blinding description

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 Street, Shahid Chamran High Way

City

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Province

Tehran

Postal code

1985717443

Approval date

2020-09-20, 1399/06/30

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.213

Health conditions studied

1

Description of health condition studied

ischemic stroke

ICD-10 code

163.9

ICD-10 code description

ischemic stroke

Primary outcomes

1

Description

Changes in the neuron-specific enolase between two arms of the study

Timepoint

Before intervention and 3 days after intervention

Method of measurement

EIA kit for the measurement of neuron-specific enolase

Secondary outcomes

1

Description

National Institutes of Health Stroke Scale

Timepoint

Daily until hospital discharge

Method of measurement

National Institutes of Health Stroke Scale questioner

2

Description

Barthel index

Timepoint

3 months after stroke

Method of measurement

Barthel index questioner

Intervention groups

1

Description

Intervention group: Patients receiving 600000 international unit of intramuscular vitamin D in day 0

Category

Treatment - Drugs

2

Description

Control group: Patients receiving standard treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology clinic, Imam Hussein hospital

Full name of responsible person

Omid Hesami

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tahereh Shams

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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

Omid Hesami

Position

Neurologist / Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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