Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ۴۰ 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
Tehran
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
Shahid Madani Street
City
Tehran
Province
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Postal code
1617763141
Phone
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Tomyseti2009@yahoo.com
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http://www.ehmc.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahereh Shams
Street address
Shahid Beheshti medical University, aarabi St., Yemen St., chamran Hwy, Velenjak St.
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Phone
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info@sbmu.ac.ir
Web page address
http://pharmacy.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
Omid Hesami
Position
Neurologist / Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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Name of organization / entity
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Mohammad Sistanizad
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Associate Professor / Clinical Pharmacy Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway

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Person responsible for updating data

Contact

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Iranshahi setare

Position

Pharmacy student

Latest degree

Medical doctor

Other areas of specialty/work

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Web page address

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