# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Effect of vitamin D on short-term prognosis of acute ischemic stroke

### Protocol summary

**Study aim**
Effect of vitamin D on short-term prognosis of acute ischemic stroke
**Design**
Clinical trial with control group, with parallel groups, randomized, phase 3 on 40 patients, randomization list through www. sealedenvelope.com/simple-randomiser/v1/lists
**Settings and conduct**
Patients with acute ischemic stroke referred to Shahid Beheshti hospital clinic in Kashan will be randomly divided into two intervention groups (receive a single dose of vitamin D + standard treatment) and control (standard treatment). MRS will be evaluated and recorded for all patients at the beginning of the study, and in order to measure the level of vitamin D, a larger sample volume of 2 to 3 cc will be taken and sent to the hospital laboratory. In addition to standard treatments, patients in the intervention group receive a single dose of intramuscular vitamin D injection (300,000 IU) up to 24 hours from the onset of symptoms, and patients in the control group receive standard treatment. After six weeks, vitamin D levels and Modified Rankin Scale (MRS) will be measured and compared for both groups.
**Participants/Inclusion and exclusion criteria**
Patients over 18 years old with acute ischemic stroke
**Intervention groups**
Intervention group: single dose intramuscular vitamin D injection (300,000 IU) + standard treatment Control group: standard treatment
**Main outcome variables**
disability severity (MRS)

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20220702055334N1**
Registration date: **2022-07-11, 1401/04/20**
Registration timing: **prospective**

Last update: **2022-07-11, 1401/04/20**
Update count: **0**
**Registration date**
2022-07-11, 1401/04/20

**Registrant information**
**Name**
Arezoo Jafarian yazdi
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2022-07-23, 1401/05/01
**Expected recruitment end date**
2023-04-21, 1402/02/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effect of vitamin D on short-term prognosis of acute ischemic stroke

**Public title**
Effect of vitamin D on short-term prognosis of acute ischemic stroke
**Purpose**
Supportive
**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients over 18 years of age with acute ischemic stroke diagnosed by clinical examination and CT scan findings
**Exclusion criteria:**
Admission after 24 hours from the onset of symptoms NIHSS >15 at admission being treated with vitamin D (at least the last 3 months) Receive alteplase History of malignancy

**Age**
From **19 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **40**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
First, the intervention group was coded with the letter A and the control group with the letter B, and then using the website www. sealedenvelope.com/simple-randomiser/v1/lists randomization list was prepared by selecting a sample size of 40 (two groups of 20) and permuted block randomization method (block size=4) (10 blocks of 4). Then, through the obtained randomization list, the subjects included in the study will be assigned to one of the two groups A or B. For example, suppose that in the first four blocks, the permutation method is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples to group B and the same will continue until the last sample (40th person).

**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 Kashan University of Medical Sciences

**Street address**
Qutb Ravandi Boulevard - Kashan University of Medical Sciences

**City**
Kashan

**Province**
Isfehan

**Postal code**
8715981151

**Approval date**
2022-06-19, 1401/03/29

**Ethics committee reference number**
IR.KAUMS.MEDNT.REC.1401.042

## Health conditions studied

### 1

**Description of health condition studied**
Acute ischemic stroke

**ICD-10 code**
I63

**ICD-10 code description**
Cerebral infarction

## Primary outcomes

### 1

**Description**
Disability severity (MRS)

**Timepoint**
At the beginning of the study, six weeks after the intervention

**Method of measurement**
MRS specific scoring system

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Intervention group patients up to 24 hours from the onset of symptoms in addition to standard treatments (including antiplatelet (aspirin 325 mg stat and 80 mg daily), lipid lowering agent (atorvastatin 80 mg acetate and 40 mg twice a day), hydration (an average of 1.5 L normal daily saline) and pantoprazole (40 mg daily) according to the conditions of each patient), are subjected to a single dose of intramuscular vitamin D injection (300,000 IU) from Osveh made in Iran.

**Category**
Treatment - Drugs

### 2

**Description**
Control group: Standard treatment Including antiplatelet (aspirin 325 mg stat and 80 mg daily), lipid lowering agent (atorvastatin 80 mg acetate and 40 mg twice a day), hydration (an average of 1.5 L normal daily saline) and pantoprazole (40 mg daily) according to the conditions of each patient

**Category**
Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
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**Full name of responsible person**
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## Sponsors / Funding sources

**1**

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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Kashan 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**
Kashan University of Medical Sciences
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Arezoo Jafarian Yazdi
**Position**
Resident
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## Person responsible for updating data

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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