

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Therapeutic effects of calcitriol on inflammatory markers and improvement of neurological symptoms in stroke patients

#### Protocol summary

##### Summary

This is a randomized, double-blind clinical trial aimed to investigate the effects of calcitriol on neurological outcomes, oxidative stress and inflammatory parameters of 80 ischemic stroke referring Shahid Beheshti hospital in Kashan. Design: Inclusion criteria: patients with acute ischemic stroke symptoms age between 20 and 85 years. Exclusion criteria: Hemorrhagic stroke patients, daily intake of vitamin D3 (more than 800IU), high serum/urinary calcium level, high blood sugar, deep coma, pregnancy. Sample size of the study: 80 patients with stroke who referred to the Shahid Beheshti Hospital in Kashan University of Medical Sciences, Kashan, Iran, will be enrolled in the study. Intervention: case group received single oral dose of 10 ug calcitriol and control group (40 patients) will receive medium change triglyceride as placebo. Blood samples were collected at admission and 24 hours after intervention in order to determine oxidative stress and inflammatory biomarkers.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017012532174N1**

Registration date: **2017-06-06, 1396/03/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-06, 1396/03/16

##### Registrant information

##### Name

Abolfazl Azami Tameh

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5562 1158

##### Email address

aazami@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research and innovation, Kashan University of Medical Sciences, project code 9586

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Therapeutic effects of calcitriol on inflammatory markers and improvement of neurological symptoms in stroke patients

##### Public title

stroke treatment

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: acute ischemic stroke; age 20-85 years old Exclusion Criteria: Hemorrhagic stroke; Vitamin D supplementation more than 800IU; High levels of calcium or phosphorus; Deep Coma

##### Age

From **20 years** old to **85 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 80

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kashan University of Medical Sciences

##### Street address

Qotb -e Ravandi Blvd.

##### City

Kashan

##### Postal code

8715988141

#### Approval date

2016-12-08, 1395/09/18

#### Ethics committee reference number

lr.kaums.rec.1395.89

## Health conditions studied

### 1

#### Description of health condition studied

Cerebral infarction

#### ICD-10 code

I63.9

#### ICD-10 code description

Cerebral infarction, unspecified

## Primary outcomes

### 1

#### Description

Infact volume

#### Timepoint

before and 3 months after intervention

#### Method of measurement

CT- Scan

### 2

#### Description

Vitamine D

#### Timepoint

Before and 72 hours after intervention

#### Method of measurement

ELISA

### 3

#### Description

Calpain 1

#### Timepoint

Before and 24 hours after intervention

#### Method of measurement

flowcytometry

### 4

#### Description

IL-6

#### Timepoint

Before and 24 hours after intervention

#### Method of measurement

Real time PCR

### 5

#### Description

IL-1b

#### Timepoint

Before and 24 hours after intervention

#### Method of measurement

Real time PCR

### 6

#### Description

TNF-a

#### Timepoint

Before and 24 hours after intervention

#### Method of measurement

Real time PCR

### 7

#### Description

HSP27

#### Timepoint

Before and 24 hours after intervention

#### Method of measurement

ELISA

### 8

#### Description

TLR4

#### Timepoint

Before and 24 hours after intervention

#### Method of measurement

Real time PCR and flowcytometry

## 9

### Description

MDA

### Timepoint

Before and 24 hours after intervention

### Method of measurement

ELISA

## 10

### Description

NO

### Timepoint

Before and 24 hours after intervention

### Method of measurement

ELISA

## 11

### Description

TAC

### Timepoint

Before and 24 hours after intervention

### Method of measurement

ELISA

## 12

### Description

TLR2

### Timepoint

Before and 24 hours after intervention

### Method of measurement

Real time PCR and flowcytometry

## Secondary outcomes

### 1

#### Description

Hypercalcemia

#### Timepoint

Before and 24 hours after intervention

#### Method of measurement

ELISA

### 2

#### Description

Hyperphosphatemia

#### Timepoint

Before and 24 hours after intervention

#### Method of measurement

ELISA

## Intervention groups

### 1

#### Description

Intervention: case group received single oral dose of 10 ug calcitriol and control group (40 patients) will receive

medium change triglyceride as placebo.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital, Kashan University of Medical Sciences

##### Full name of responsible person

Dr. Ebrahim Kuchaki

##### Street address

Pezeshk Blvd, Qotbe Ravandi Blvd

##### City

Kashan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor of research and innovation

##### Full name of responsible person

Dr. Ghalamali Hamidi

##### Street address

Qotb -e Ravandi Blvd.

##### City

Kashan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor of research and innovation

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Department of Anatomy, School of Medicine, Kashan University of Medical Sciences,

#### Full name of responsible person

Dr. Abolfazl Azami Tameh

#### Position

Associate professor

#### Other areas of specialty/work

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**Full name of responsible person**

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**Position**

Associate professor

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aazami@kaums.ac.ir

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*