

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

Street address

School of Medicine, Kashan University of Medical Sciences

City

Kashan

Postal code

8715988141

Phone

+98 31555621157

Fax**Email**

aazami@kaums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Anatomical Sciences Research Center, Kashan University of Medical Sciences

Full name of responsible person

Dr. Abolfazl Azami Tameh

Position

Ph.D

Other areas of specialty/work**Street address**

School of Medicine, Kashan University of Medical Sciences

City

Kashan

Postal code

8715988141

Phone

+98 31555621158

Fax**Email**

aazami@kaums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Abolfazl Azami Tameh

Position

Associate professor

Other areas of specialty/work**Street address**

Qotb -e Ravandi Blvd.

City

Kashan

Postal code

8715988141

Phone

+98 31555621158

Fax**Email**

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