Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
Ir.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
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Person responsible for updating data

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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