Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of calcitriol on serum level of inflammatory biomarkers in patients with ischemic stroke

Protocol summary

Study aim
Evaluation of the effectiveness of rocaltrol in reducing inflammatory factors after stroke

Design
This study is a randomized, double-blind clinical trial of 78 patients with ischemic stroke. They have been hospitalized. Patients are randomly divided into intervention and control groups. The allocation of patients in the control and intervention groups is a random block.

Settings and conduct
This study will be performed on patients with ischemic stroke referred to Farshchian, Sina and Beheshti hospitals in Hamadan. In the intervention group, patients are prescribed oral calcitriol at a dose of 1 microgram once a day for 5 days in addition to the standard treatment. In the control group, patients receive a placebo in addition to the standard treatment. Then the inflammatory factors of ischemic stroke are measured at the beginning of the study (before receiving the drug) and 3 days after receiving the drug or at the end of the study.

Participants/Inclusion and exclusion criteria
The study population consisted of patients in whom the diagnosis of acute ischemic stroke was confirmed and hospitalized in the first 24 hours after the stroke. going out.

Intervention groups
In the intervention group, patients are prescribed oral calcitriol at a dose of 1 microgram once a day for 5 days in addition to the standard treatment. In the control group, patients receive a placebo in addition to the standard treatment. Then the inflammatory factors of ischemic stroke are measured at the beginning of the study (before receiving the drug) and 3 days after receiving the drug or at the end of the study.

Main outcome variables
Erythrocyte Sedimentation Rate؛ C-reactive protein

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210101049905N1**
Registration date: **2021-01-15, 1399/10/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-15, 1399/10/26**
Update count: **0**

Registration date
2021-01-15, 1399/10/26

Registrant information
Name
Mahdi Mahanpoor
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 86 3224 2129
Email address
mahdymahanpoor19@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-01-04, 1399/10/15
Expected recruitment end date
2022-02-20, 1400/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluating the effect of calcitriol on serum level of inflammatory biomarkers in patients with ischemic stroke

Public title
Effect of Clcitriol in Ischemi stroke
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 85 years Focal neurological disorder Clinical diagnosis of acute ischemic stroke Radiological findings of MRI and CT are consistent with the clinical diagnosis of acute hemisphere stroke No other concomitant inflammatory disease Do not take drugs other than standard ischemic stroke treatments that alter the levels of the factors under consideration. No pregnancy and lactation Patients who have been hospitalized for the first 24 hours after a stroke. Patients suffering from ischemic stroke for the first time Do not use any combination with antioxidant effects in the past month No asthma and a history of anaphylactic shock
Exclusion criteria:
Evidence based on acute or chronic intracerebral hemorrhage and cerebral aneurysm Existence of any etiology other than ischemia Existence of any cognitive or behavioral disorders that lead to the patient not cooperating. The patient's unwillingness to continue cooperating or taking the drug correctly Drug intolerance and side effects Consumption of any combination or drug with antioxidant effects except prescription drugs
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into intervention and control groups. The allocation of patients in the control and intervention groups is a random block, so that we put 2 sheets A and two sheets B in an envelope, and each time we remove one of the sheets, we place the patient in the control or intervention group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients are randomly divided into intervention and control groups. The allocation of patients in the control and intervention groups is a random block, so that we put 2 sheets A and two sheets B in an envelope, and each time we remove one of the sheets, we place the patient in the control or intervention group. The sheet is removed and will not be returned to the envelope until the sheets in the envelope are finished.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Research Ethics Committee,Vice Chancellor for Research and Technology, Medical Sciences university,Shahid Fahmideh Blvd.,
City
Hamedan
Province
Hamadan
Postal code
6517838678
Approval date
2020-12-19, 1399/09/29
Ethics committee reference number
IR.UMSHA.REC.1399.776

Health conditions studied

1

Description of health condition studied
Ischemic Stroke
ICD-10 code
I63.00
ICD-10 code description
Cerebral infarction due to thrombosis of unspecified precerebral artery

Primary outcomes

1

Description
Erythrocyte Sedimentation Rate
Timepoint
At the beginning of the study and 3 days after the end of the medication
Method of measurement
Westergren

2

Description
C-Reactive Protein
Timepoint

At the beginning of the study and 3 days after the end of the medication

Method of measurement

latex agglutination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After diagnosis by the relevant specialist and the existence of inclusion criteria and obtaining consent, patients are randomly divided into two intervention or control groups. The objectives of the study will be explained to the patients participating in the study and for the patients of the two groups receiving the drug and placebo, the possible beneficial effects, possible side effects and how to use the drug will be explained and only patients will enter the study with informed consent. In this study, patients with unconsciousness will enter the study with the consent of first-degree relatives. Patients will not be included in the study if patients do not have the conditions of full intellect and will and it is not possible to obtain the consent of their partner and guardian (father or paternal grandfather). Calcitriol and placebo are prepared orally. The consent form is given in Appendix 1. In the intervention group, patients are prescribed oral calcitriol at a dose of 1 microgram once a day for 5 days in addition to the standard treatment.

Category

Treatment - Drugs

2

Description

Control group: After diagnosis by the relevant specialist and the existence of inclusion criteria and obtaining consent, patients are randomly divided into two groups of intervention or control. The objectives of the study will be explained to the patients participating in the study and for the patients of the two groups receiving the drug and placebo, the possible beneficial effects, possible side effects and how to use the drug will be explained and only patients will enter the study with informed consent. In this study, patients with unconsciousness will enter the study with the consent of first-degree relatives. Patients will not be included in the study if patients do not have the conditions of full intellect and will and it is not possible to obtain the consent of their partner and guardian (father or paternal grandfather). Calcitriol and placebo are prepared orally. The consent form is given in Appendix 1. In the control group, patients receive placebo aqueous solution in addition to standard treatment

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

farshchian,sina and beheshti hospitals

Full name of responsible person

Mahdi Mahanpoor

Street address

No. 3873, Lale deadend, Olke alley, Imam khomeini street

City

Arak

Province

Markazi

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3813783873

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Email

mahdymahanpoor19@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Vice Chancellor for Research and Technology, Medical Sciences university,Shahid Fahmideh Blvd.,

City

hamedan

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Hamadan

Postal code

6517619657

Phone

+98 81 3838 0717

Fax

+98 81 3838 0130

Email

Fanavari@umsha.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research and Technology of Hamadan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mahdi Mahanpoor

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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