Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between calcitriol and placebo on serum interleukin 6 level, stroke severity, infarct volume and clinical outcomes in patients with ischemic stroke

Protocol summary

Study aim

Evaluation of the effect of calcitriol on serum interleukin 6 levels in order to reducing stroke severity, infarct volume and improving clinical outcomes in ischemic stroke patients

Design

This study is a randomized, double-blind clinical trial of 78 patients with ischemic stroke.The study population consists of patients who have been confirmed to have an acute ischemic stroke and are hospitalized within the first 24 hours after the stroke. The allocation of patients in the control and intervention groups will be done using a random block method.

Settings and conduct

This study will be performed on patients with ischemic stroke referred to Besat Hospital in Hamadan. The study population will be patients in whom the diagnosis of acute ischemic stroke will be confirmed and hospitalized in the first 24 hours after stroke. This study will be performed randomly and double blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have been diagnosed with acute ischemic stroke; patients who have been hospitalized in the first 24 hours after stroke. Non-inclusion criteria: presence of another reason for cerebral artery occlusion other than stroke

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 placebo aqueous solution in addition to standard treatment.

Main outcome variables

Interleukin 6; National Institutes of Health Stroke Scale score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210101049905N2**
Registration date: **2021-11-22, 1400/09/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-22, 1400/09/01**
Update count: **0**

Registration date

2021-11-22, 1400/09/01

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

2021-11-11, 1400/08/20

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
Comparison between calcitriol and placebo on serum interleukin 6 level, stroke severity, infarct volume and clinical outcomes 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 Patients who have been hospitalized for the first 24 hours after a stroke. Patients suffering from ischemic stroke for the first time
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. Consumption of any combination or drug with antioxidant effects except prescription drugs Existence of another concomitant inflammatory disease Taking medications other than standard ischemic stroke treatments that alter the levels of the factors under consideration. Pregnancy and lactation Use any combination with antioxidant and anti-inflammatory effects in the past month Asthma and a history of anaphylactic shock Taking drugs that interfere with calcitriol
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Data and Safety Monitoring Board

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 through random block method, so that we put 2 sheets A and two sheets B in an envelope, and each time we remove one of the sheets and determine the group for the patient. The sheet is taken out and will not be returned to the envelope until the sheets in the envelope will be 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, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd.,
City
Hamedan
Province
Hamadan
Postal code
6517838678
Approval date
2021-07-10, 1400/04/19
Ethics committee reference number
IR.UMSHA.REC.1400.307

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
Interleukin 6
Timepoint
At the beginning of the study and 3 days after the end of the medication
Method of measurement
ELISA test

2

Description
National Institutes of Health Stroke Scale score
Timepoint
At the beginning of the study and 90 days after the end of the medication
Method of measurement
NIHSS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, in addition to the standard treatment, Dana Company's oral calcitriol is prescribed to patients at the dose of 1 microgram once a day for 5 days.
Category
Treatment - Drugs

2

Description
Control group: In the control group, patients receive aqueous placebo solution produced by Dana company in addition to the standard treatment
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat hospital
Full name of responsible person
Mahdi Mahanpoor
Street address
Hokama Street, Shahid Motahari Blvd.
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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; Hamedan University of Medical Sciences; Shahid Fahmideh Blvd.
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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
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 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