Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Assessment of the effect of nano-curcumin oral intake on clinical signs and serum IL-6 levels in patients with ischemic stroke: Double-blind Clinical Trial

Protocol summary

Study aim

The effect of nano curcumin treatment on clinical symptoms and serum level of inflammatory factor IL-6 in patients with ischemic cerebral stroke.

Design

A randomized, controlled, double-blind, placebo-controlled clinical trial

Settings and conduct

Forty patients referred to the neurology department of Poursina Hospital in Rasht with ischemic stroke symptoms confirmed by CT-Scan. Then patients were randomly divided into two groups of 20 nanocurcumin and control and into Four-person blocks . This was done by Ms. Samaneh Shirkoohi (patients, assessors and physicians did not know the individuals in each group). The curcumin group will receive a single 80 mg capsule of nano-micelles of curcumin daily (Cina Curcumin ®, Exir Nano Sina Co.) for one month, and the control group will receive curcumin placebo for 1 month. All patients will be monitored for one month.Blood samples will be taken before and after the end of treatment for one month. The blood factor IL-6 will be measured using ELISA kit in both curcumin and placebo groups. The data will be analyzed as per protocol.

Participants/Inclusion and exclusion criteria

inclusion: Patients with ischemic stroke less than a week after their stroke with NIHSS <=20 and MRS<=4
exclusion: Cerebral Venous Thrombosis Hemorrhagic infarction

Intervention groups

The curcumin group will receive a single 80 mg capsule of nano-micelles of curcumin daily (Sina Curcumin ®, Exir Nano Sina Co.) for 1 month, and Control group will receive curcumin placebo (capsule containing 80 polycarbate produced by Exir Nanosina) for 1 month.

Main outcome variables

The National Institute of Health Stroke Scale (NIHSS) questionnaire The blood level of Inflammatory factor IL-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091108002680N3**
Registration date: **2020-02-24, 1398/12/05**
Registration timing: **prospective**

Last update: **2020-02-24, 1398/12/05**
Update count: **0**

Registration date

2020-02-24, 1398/12/05

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

0131-3227346

Email address

a_saberi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment of the effect of nano-curcumin oral intake on clinical signs and serum IL-6 levels in patients with ischemic stroke: Double-blind Clinical Trial

Public title
Assessment of the effect of nano-curcumin oral intake on clinical signs and serum IL-6 levels in patients with ischemic stroke: Double-blind Clinical Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Ischemic CVA less than 1 week from their symptoms begin National Institutes of Health Stroke Scale (NIHSS) <= 20 Modified Rankin Scale (MRS) <= 4

Exclusion criteria:
Cerebral Venous Thrombosis Hemorrhagic infarction Internal capsule and Middle Cerebral Artery trunk infarction History of gall bladder stone or bile duct stenosis Gastroesophageal reflux disease or active peptic ulcer Use of NSAIDs or Reserpine Using anticoagulant or thrombolitic agent in last 24 hours Using of Warfarin in last 1 week Dissatisfaction More than 1 week from symptoms begin

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization is used for randomization.The blocks are fixed and 4 in size that the first 2 will be in the curcumin group and the second 2 will be in the placebo group

Blinding (investigator's opinion)
Double blinded

Blinding description
Individuals under study, physicians and those assessing outcomes are kept blind to specific study groups. After selecting patients, medications are given to patients in unnamed and similar envelopes by Ms. Samaneh Shirkoohi, and the list of patients in each group will not be disclosed until the end of the data analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of gilan University of Medical Sciences

Street address
Neuroscience Research Center, Pursina Hospital, Nursing Street

City
rasht

Province
Guilan

Postal code
41937-13194

Approval date
2019-08-03, 1398/05/12

Ethics committee reference number
IR.GUMS.REC.1398.222

Health conditions studied

1

Description of health condition studied
Ischemic cerebral stroke

ICD-10 code
I64

ICD-10 code description
Stroke, non specified as haemorrhage or infarction

Primary outcomes

1

Description
Blood levels of inflammatory factor interleukin-6

Timepoint
Before treatment and after 1 month

Method of measurement
ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: capsule nano-curcumin (sina curcumin) 80 mg Daily for 1 month

Category
Treatment - Drugs

2

Description
Control group: Capsules containing polycarbate 80 are quite similar to the main drug Daily for 1 month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina Hospital
Full name of responsible person
Zeinab Ehtiatkar
Street address
Neuroscience Research Center, Pursina Hospital, Nursing Street
City
Rasht
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Guilan
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41937-13194
Phone
+98 13 3332 2444
Email
Ze.ehtiatkar@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr. Shadman Nemati
Street address
Rasht - Namjoo Street - Shahid Siadati Street - Opposite 17 Shahrivar Hospital - Old School of Health - Vice Chancellor for Research and Technology
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Doctor Alia Saberi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Zeinab Ehtiatkar

Position

Resident of Neurology

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Title and more details about the data/document

After the end of the study period

When the data will become available and for how long

After the end of the study period

To whom data/document is available

Once the results are published as an article, they will be made public

Under which criteria data/document could be used

If published as an article

From where data/document is obtainable

Guilan University of Medical Sciences Neuroscience Research Center

What processes are involved for a request to access data/document

Visiting to Neuroscience Research Center of Guilan University of Medical Sciences

Comments