

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
thrombolytic 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 polycarbonate 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, Poursina Hospital,
Nursing Street

City

Rasht

Province

Guilan

Postal code

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

City

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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

Street address

Neuroscience Research Center, Poursina Hospital,
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a_saberi@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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Position

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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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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