

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Efficacy and Safety of nano-curcumin on the clinical condition of patients with hemorrhagic stroke: A randomized, assessor-blind, parallel-group pilot study

Protocol summary

Study aim

Efficacy and Safety of nano-curcumin on the clinical condition of patients with hemorrhagic stroke

Design

A randomized, assessor-blind, parallel-group pilot study. Phase 2 is performed on 40 patients with hemorrhagic stroke who are divided into two groups. The intervention group (20 patients) in addition to the main treatment of hemorrhagic stroke, receive nano-curcumin 80 mg daily and the control group (20 patients) receive only their main treatment. Excel software rand function was used for randomization.

Settings and conduct

Within 24 hours after the start of ICH, the control group will receive their routine treatments and the intervention group, in addition to routine and standard treatments, will be prescribed 80 mg curcumin capsules and will continue to 12 weeks. Place of study: Bu Ali Hospital in Sari city

Participants/Inclusion and exclusion criteria

Age 80-18 years, diagnosis of ICH with CT scan of the brain, NIHSS > 4 and MRS < 2 presymptomatic, bleeding in the putamen area, Glasgow criterion (GCS greater than 8) and informed consent of the patient or first-degree relatives. Allergy to turmeric, no pregnancy, no liver enzymes more than three times of normal range and kidney disease or creatinine more than 2, no candidate for surgery and hematoma evacuation, no secondary ICH to anticoagulants and tumor and aneurysm and AVM, no infratentorial bleeding, Platelet count < 75,000 / mm³, INR < 1.4,

Intervention groups

Intervention group: Routine treatment in addition to nanocurcumin 80 mg daily. Control group: Routine treatment.

Main outcome variables

Disability and dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140221016666N4**

Registration date: **2020-11-30, 1399/09/10**

Registration timing: **prospective**

Last update: **2020-11-30, 1399/09/10**

Update count: **0**

Registration date

2020-11-30, 1399/09/10

Registrant information

Name

Narges Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3311 6275

Email address

n.karimi@mazums.ac.ir

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

Efficacy and Safety of nano-curcumin on the clinical condition of patients with hemorrhagic stroke: A randomized, assessor-blind, parallel-group pilot study

Public title

Efficacy and safety of nano-curcumin on the clinical condition of patients with hemorrhagic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-80 years, Diagnosis of ICH by brain CT scan, NIHSS > 4 and MRS < 2 presymptomatic, bleeding in the putamen area, Glasgow criterion (GCS greater than 8) informed consent of the patient or first-degree relatives.

Exclusion criteria:

Allergy to turmeric, pregnancy, liver disease with liver enzyme more than three times of normal range kidney disease or creatine more than 2, candidate for surgery and hematoma evacuation, secondary ICH for anticoagulant use and tumor and aneurysm and AVM, intratentorial hemorrhage, platelet count / 75,000 mm³ <, INR < 1.4, fever at initial visit, other inflammatory diseases including pneumonia, hematology, rheumatology, urinary tract infection on admission. Immune suppressant drugs,] absorption syndromes, history of diabetes, smoking, alcohol and drug use

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sample selection is based on block balance randomization with 4 blocks. The intervention and control groups are named A and B so that from the four blocks that will be shown in 6 states (AABB, BBAA, ABAB, BABA, ABBA, BAAB and using the table of random numbers, the row of blocks will be selected.

Blinding (investigator's opinion)

Single blinded

Blinding description

The physician evaluating the patient will be blind. In this study, the physician who gives the medicine to the patients and the patients or participants are not blind and know the type of treatment but the assessors who examine patients and complete the questionnaire are blind and do not know the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moalem square, Sari City

City

Sari

Province

Mazandaran

Postal code

4815838477

Approval date

2020-10-11, 1399/07/20

Ethics committee reference number

IR.MAZUMS.REC.1399.718

Health conditions studied

1

Description of health condition studied

Intracerebral hemorrhage

ICD-10 code

I61

ICD-10 code description

Nontraumatic intracerebral hemorrhage

Primary outcomes

1

Description

Improvement of the patient's disability and dysfunction to achieve MRS is below 3

Timepoint

At the time of admission, 24, 48 and 72 hours, 1 week (or last day of hospitalization), 4 weeks and 12 weeks

Method of measurement

MRS questionnaire

Secondary outcomes

1

Description

Reduce NIHSS to less than the initial 50% and reduce hematoma volume and increase Glasgow score

Timepoint

At the time of admission, 24, 48 and 72 hours, 1 week (or last day of hospitalization), 4 weeks and 12 weeks

Method of measurement

Hematoma size is measured using the formula $ABC / 2$ (A: The largest diameter in the largest bleeding slice, B

the diameter perpendicular to A and C, the approximate number of 10 mm slices in which bleeding occurs). NIHSS Questionnaire and Glasgow scale

Intervention groups

1

Description

Intervention group: Nano-curcumin medication with dosage of 80 mg for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Patients with cerebral hemorrhage without medication

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bou ali Sina hospital

Full name of responsible person

Narges Karimi

Street address

Bou ali Sina hospital, Pasradan Boulevard, Sari city

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Drkarimi_236@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Vice President for Research and Technology

Street address

Sari, Moallem Square, Deputy of 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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Narges Karimi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Full name of responsible person

Narges Karimi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

At the request of a scientific and academic reference

From where data/document is obtainable

Narges Karimi, Drkarimi_236@yahoo.com

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

By accepting the University Ethics Committee, data can be provided

Comments