Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of Nano Micelle curcumin of patient with ischemic stroke: triple-blind placebo-controlled randomized clinical trial

Protocol summary

Study aim
to evaluate the efficacy of curcumin in acute ischemic stroke patients

Design
Triple blind randomized placebo-controlled clinical trial, parallel groups, superiority, intention to treat.

Settings and conduct
Patients with acute ischemic stroke who referred to Ghaem hospital, Affiliated to Mashhad University of Medical Sciences (MUMS), Will be recruited into this clinical trial. Participants will be blinded and randomly be assigned to placebo and intervention groups with 1:1 allocation ratio. Placebo and intervention groups will receive placebo and 80mg of curcumin once a day for 8 weeks, respectively. Patients will be examined by blind evaluators 4day, 8 weeks and 3-month after the study commencement.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 50-80 years First ever stroke patients Ischemic stroke GCS<13 NIHSS=4-25 MRS<2 before the stroke Stroke occurrence within prior 12 hours. Exclusion criteria: Fever Presence of inflammatory conditions The use of immunosuppressive agents Death within the first week of stroke occurrence Presence of bedsore during follow-up Myocardial infarction during the study period Pregnancy TIA within last 3-month Massive cerebral infarction Not consenting to participate History of sensitivity to Turmeric Advanced hepatic diseases Malabsorption syndrome History of diabetes Receiving rTPA Mechanical thrombectomy during the study History of dementia Craniotomy during the study 35<BMI History of cigaret smoking and alcohol consumption

Intervention groups
The intervention group will receive 80mg of curcumin once a day for 8 weeks including the routine acute ischemic stroke treatments. The placebo group will receive a placebo, which is identical to the curcumin, once a day for 8 weeks and the routine treatment for acute ischemic stroke.

Main outcome variables
Stroke severity using NIHSS Degree of disability/dependence using MRS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180803040679N1**
Registration date: **2019-01-03, 1397/10/13**
Registration timing: **prospective**

Last update: **2019-01-03, 1397/10/13**
Update count: **0**

Registration date
2019-01-03, 1397/10/13

Registrant information

Name
reza rahimzadeh oskooie

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3841 1037

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rahimzadehr901@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-04, 1397/10/14

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Nano Micelle curcumin of patient with ischemic stroke: triple-blind placebo-controlled randomized clinical trial

Public title
effects of curcumine in stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 50-80 years First ever stroke patients Ischemic stroke GCS<13 NIHSS=4-25 MRS<2 before the stroke Stroke occurrence within prior 12 hours.
Exclusion criteria:
Fever at first presentation Presence of other inflammatory conditions Immunosuppressive drug consumption Death within the first week of the study Presence of bedsore during follow-up Occurrence of myocardial infarction during the study follow-up Pregnancy TIA 3 month prior to study Massive brain infarction Declining to participate History of allergy to Turmeric Advanced hepatic conditions malabsorption syndrome History of diabetes Receiving rTPA Mechanical thrombectomy during the study follow-up Presence of dementia Craniotomy during the study follow-up BMI more than 35 Cigarette smoking Alcohol consumption
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
This study used simple randomization. Randomization units consisted of individuals. We used closed pockets for randomization.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Study participants: patients will be divided into intervention and placebo groups. Placebo and the intervention group drugs will be identical and patients won`t notice the difference. Investigators: a group of investigators will evaluate patients. Investigators will be provided with placebo and Curcumin which are identical, However, Drugs will be labeled as A and B, Which presents each study groups. statistical analyzer: Data will present to statistical analyzers as A & B groups. They will be blinded about the intervention and placebo groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Faculty of medicine, Mashhad university of medical sciences Campus, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
91766-76757
Approval date
2018-12-24, 1397/10/03
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.513

Health conditions studied

1

Description of health condition studied
Acute ischemic stroke
ICD-10 code
I63.2
ICD-10 code description
Cerebral infarction due to unspecified occlusion or stenosis of precerebral arteries

Primary outcomes

1

Description
Stroke severity
Timepoint
before intervention, 4 days, 8 weeks and 3 month after intervention
Method of measurement
using NIHSS

2

Description
degree of disability/dependence
Timepoint
before intervention, 4 days, 8 weeks and 3 month after intervention
Method of measurement
using MRS

Secondary outcomes

1

Description
Activities of Daily Living
Timepoint
before intervention, 4 days, 8 weeks and 3 month after intervention
Method of measurement
Barthel index

2

Description
seizure
Timepoint
before intervention, 4 days, 8 weeks and 3 month after intervention
Method of measurement
according to clinical presentations

Intervention groups

1

Description
Intervention group: The intervention group will receive 80mg of Curcumin pearl everyday for 8 weeks accompanied with acute ischemic stroke treatments. The first dose will be administered during the first 12 hour of ischemic stroke occurrence. The brand name is SinaCurcumin®. Marketing Authorization holder is Exir Nano Sina Co. and the drug is manufactured by Minoo Co. IRC: 1228225765
Category
Treatment - Drugs

2

Description
Control group: The control group will receive a placebo, which is identical to the curcumin, once a day for 8 weeks and the routine treatment for acute ischemic stroke.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Fariborz Rezaeitalab
Street address
Ahmad Abad Ave, Shariatie Square
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Mashhad
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Razavi Khorasan
Postal code
91766-99199
Phone
+98 51 3840 0000
Email
rahimzadehr901@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Fariborz Rezaeitalab
Street address
Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94)
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Razavi Khorasan
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Phone
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Email
rahimzadehr901@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Fariborz Rezaeitalab

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

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No 46, Qods 14, Felestin Ave

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Person responsible for scientific inquiries

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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Neurology

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Reza Rahimzadeh Oskooie

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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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
Not applicable

Analytic Code
Yes - There is 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
these files will be presented upon request: Patients` data after removing their identity, Research protocol, statistical methods used in this study and written informed consent.

When the data will become available and for how long
data will be available 3 months after the article has been published

To whom data/document is available
Any researcher who needs our data to accomplish his research

Under which criteria data/document could be used
The researcher should use these data only in their related research and should mention the reference

From where data/document is obtainable
researchers should send their request to Mr. Reza Rahimzadeh Oskooie via email. Email: rahimzadehr901@mums.ac.ir

What processes are involved for a request to access data/document
Researchers should send their request for data that includes their reasons for using the data and their study protocols and aims. The request will be answered during 14 business days

Comments