Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Effect of high-dose oral N-acetylcysteine versus placebo on serum level of inflammatory cytokines in patients with ischemic stroke: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of high-dose oral N-acetylcysteine versus placebo on serum level of inflammatory cytokines in patients with ischemic stroke

Design
This a double-blind randomized clinical trial, phase II, in which 100 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible patients with ischemic stroke who will refer to Sina Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 85 years Ischemic stroke Stroke for the first time Local neurologic disorder Hospitalization within the first 24 hours after stroke Exclusion criteria: Pregnancy or breastfeeding Inflammatory disease Asthma A history of anaphylaxis shock

Intervention groups
Intervention group: Routine stroke treatment plus oral N-acetylcysteine tablet (manufactured by Hexal Pharmaceutical Co.) with a loading dose of 4 g and then 2 g every 12 hours for 2 days Control group: Routine stroke treatment plus placebo tablet (manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) with a loading dose of two tablets and then one placebo tablet every 12 hours for 2 days

Main outcome variables
Primary outcome: Measuring serum level of TNF-α before intervention and 3 days later through laboratory test Measuring serum level of IL-6 before intervention and 3 days later through laboratory test Measuring serum level of ICAM-1 before intervention and 3 days later through laboratory test Measuring serum level of NSE before intervention and 3 days later through laboratory test

General information

Reason for update
Changing the dose of medication in the intervention and control groups.

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N215**
Registration date: **2018-03-19, 1396/12/28**
Registration timing: **prospective**

Last update: **2020-01-23, 1398/11/03**
Update count: **1**

Registration date
2018-03-19, 1396/12/28

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-20, 1397/01/31

Expected recruitment end date
2019-05-21, 1398/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of high-dose oral N-acetylcysteine versus placebo on serum level of inflammatory cytokines in patients with ischemic stroke: a double-blind randomized clinical trial

Public title
Effect of high-dose oral N-acetylcysteine versus placebo on serum level of inflammatory cytokines in patients with ischemic stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 85 years Ischemic stroke Stroke for the first time Local neurologic disorder Hospitalization within the first 24 hours after stroke
Exclusion criteria:
Pregnancy or breastfeeding Inflammatory disease Asthma A history of anaphylaxis shock
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind
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
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2018-02-24, 1396/12/05
Ethics committee reference number
IR.UMSHA.REC.1396.820

Health conditions studied

1

Description of health condition studied
Ischemic stroke
ICD-10 code
I63
ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
Measuring serum level of TNF-α
Timepoint
Before intervention and 3 days later
Method of measurement
Through laboratory test

2

Description
Measuring serum level of IL-6
Timepoint
Before intervention and 3 days later
Method of measurement
Through laboratory test

3

Description
Measuring serum level of ICAM-1
Timepoint
Before intervention and 3 days later
Method of measurement
Through laboratory test

4

Description
Measuring serum level of NSE
Timepoint
Before intervention and 3 days later
Method of measurement
Through laboratory test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine stroke treatment plus oral N-acetylcysteine tablet (manufactured by Hexal Pharmaceutical Co.) with a loading dose of 4 g and then 2 g every 12 hours for 2 days
Category
Treatment - Drugs

2

Description
Control group: Routine stroke treatment plus placebo tablet (manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) with a loading dose of two tablets and then one placebo tablet every 12 hours for 2 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Maryam Sabet Ghadam
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Sina Hospital, Mirzadeh Eshghi Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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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
Hamedan 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
Dr. Maryam Mehrpoya
Position
Pharmacologist
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Person responsible for updating data

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Professor of Epidemiology

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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