Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of high-dose oral N-acetylcysteine versus placebo on serum level of oxidative and nirtosative stress and clinical outcomes 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 ofoxidative and nirtosative stress and clinical outcomes in patients with ischemic stroke

Design
This a double-blind randomized clinical trial, phase II, in which 88 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 (Tehran, Iran) during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: age: 18 to 85 years old; Ischemic stroke for the first time; local neurologic disorder hospitalization within the first 24 hours after stroke. Exclusion criteria: pregnancy or breast feeding; inflammatory disease; Asthma; history of anaphylactic shock.

Intervention groups
Intervention group: routine stroke treatment plus oral N-acetylcysteine tablet 200 g every 12 hours for 2 days. Control group: routine stroke treatment plus oral placebo every 12 hours for 2 days.

Main outcome variables
Serum level of lipid peroxidation, nitric oxide, total antioxidant capacity, thiol, activity of glutathione peroxidase, catalase, superoxide dismutase, NIHSS, mRS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150629022965N16**
Registration date: **2018-07-15, 1397/04/24**
Registration timing: **prospective**

Last update: **2020-02-06, 1398/11/17**
Update count: **2**

Registration date
2018-07-15, 1397/04/24

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-22, 1397/04/31

Expected recruitment end date
2019-04-20, 1398/01/31

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 oxidative and nirtosative stress and clinical outcomes 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 oxidative and nirtosative stress and clinical outcomes in patients with ischemic stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age: 18 to 85 years old Ischemic stroke Stroke for the first time Local neurologic disorder Patients who have been admitted for the first 24 hours after the stroke
Exclusion criteria:
Pregnancy or breastfeeding Inflammatory disease Asthma History of anaphylaxis shock
Age
From **18 years** old to **85 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **88**
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 Hamedan University of Medical Sciences
Street address
Pharmacy school, Hamadan University of Medical Sciences, in front of Mardom park, Shahid Fahmideh Blvd., Hamedan
City
Hamedan
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Hamadan
Postal code
6517838678
Approval date
2018-06-08, 1397/03/18
Ethics committee reference number
IR.UMSHA.REC.1397.136

Health conditions studied

1

Description of health condition studied
ischemic stroke
ICD-10 code
163
ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
Serum level of lipid peroxidation
Timepoint
Before intervention and 3 days after intervention
Method of measurement
kit

2

Description
Serum levels of nitric oxide
Timepoint
Before intervention and 3 days after intervention
Method of measurement
kit

3

Description
Serum levels of total antioxidant capacity
Timepoint
Before intervention and 3 days after intervention
Method of measurement
kit

4

Description
Catalase activity
Timepoint
Before intervention and 3 days after intervention
Method of measurement
kit

5

Description
Activity of superoxide dismutase
Timepoint
Before intervention and 3 days after intervention
Method of measurement
kit

6

Description
Serum level of thiol
Timepoint
Before intervention and 3 days after intervention
Method of measurement
kit

7

Description
Activity of Glutathione Peroxidase
Timepoint
Before intervention and 3 days after intervention
Method of measurement
kit

8

Description
National Institutes of Health Stroke Scale
Timepoint
Before intervention and 90 days after intervention
Method of measurement
Questionnaire

9

Description
Modified Rankin Scale for Neurologic Disability
Timepoint
Before intervention and 90 days after intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: routine stroke treatment plus oral N-acetylcysteine tablet 200 mg with 4 g loading dose,after 18-24 h 4g,every 12 hours 2g for 2 days
Category
Treatment - Drugs

2

Description
Control group: routine stroke treatment plus oral placebo with 4 g loading dose,after 18-24 h 4g,every 12 hours 2g for 2 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamedan Farshchian Sina Hospital
Full name of responsible person
Maryam Mehrpooya
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Maryam Mehrpooya
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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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