

# 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- $\alpha$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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- $\alpha$

**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

##### Street address

Sina Hospital, Mirzadeh Eshghi Ave.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3827 4184

##### Email

maryana.sbt@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bashirian

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3838 0717

##### Email

info.research@umsha.ac.ir

#### 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

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Sina Hospital, Mirzadeh Eshghi Ave.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3827 4184

##### Email

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Mehrdokht Mazdeh

**Position**

Neurologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

**Street address**

Sina Hospital, Mirzadeh Eshghi Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3827 4184

**Email**

mehrdokhtmazdeh@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

## 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