# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 2026

## Evaluation of the neuroprotective effect of N-Acetyl-Cysteine in patients with cerebrovascular accident in years 95-96 in firoozgar hospital.

## Protocol summary


**Summary**

The study goal is Evaluation of the neuroprotective effect of N-Acetyl-Cysteine in patients with cerebrovascular accident in years 95-96 in firoozgar hospital. it is a single blind placebo controlled trial. Population study is patients admitted to stroke unit of firoozgar hospital. The main inclusion criteria are patients with mild to moderate first attack of CVA admitted within 24 hours of symptom onset. The main exclusion criteria are allergy to N-acetyl- cysteine, severe hepatic or renal failure and patients who received r-tPA. Study sample size which is sum of both control and treatment group is 60 patients. N- acetyl- cysteine is given to treatment group in addition to standard CVA treatment. Patients in control group only received standard CVA treatment. Intervention time is first 24 hours of CVA onset. The blood sample for measuring MMP-9 marker is collected from both groups before and 24 hours after receiving N-acetyl- cysteine and standard treatment. NIHSS for the patients in both group is calculated before therapy, 24 hours, 2 weeks, 1 months and 3 months after therapy.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017011931229N2**
Registration date: **2017-02-24, 1395/12/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2017-02-24, 1395/12/06

**Registrant information**

**Name**

Azadeh Eshraghi

**Name of organization / entity**

Department of Clinical Pharmacy, Faculty of Pharmacy-International Campus, Iran University of Medica

**Country**

Iran (Islamic Republic of)

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+98 86709

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**Recruitment status**

**Recruitment complete**

**Funding source**

Iran University of Medical Sciences

**Expected recruitment start date**

2016-03-19, 1394/12/29

**Expected recruitment end date**

2018-03-20, 1396/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the neuroprotective effect of N-Acetyl-Cysteine in patients with cerebrovascular accident in years 95-96 in firoozgar hospital.

**Public title**

N- acetyl- cysteine effect in stroke treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: all admitted patients with first attack of mild to moderate CVA according to NIHSS between 0-16; admitted patients within first 24 hours of onset of CVA.
Exclusion criteria:Hemorrhagic stroke; Severe Hepatic or renal failure. ( creatinine clearance less than 30 mg/dl);

History of Vasculitis; Allergy to N- acetyl- cystein; Alzheimer or dementia due to any cause; Coexistent other neurologic disorders.;Past history of CVA;Age more than 80 years; Diseases that affect on MMP-9 level. e.g neuropsychiatric disorders like schizophrenia and bipolar disorder,epilepsy and mutiple sclerosis; Intravenous or intaarterial r-tPA injection.

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

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Iran Uinversity of Medical Sciences

**Street address**
Tehran- hemmat highway- near milad tower- iran university of medical sciences

**City**
Tehran

**Postal code**
1449614535

**Approval date**
2016-09-22, 1395/07/01

**Ethics committee reference number**
IR.IUMS.REC.1395.28001

## Health conditions studied

### 1

**Description of health condition studied**
Stroke

**ICD-10 code**
G46

**ICD-10 code description**
Vascular syndromes of brain in cerebrovascular disease

## Primary outcomes

### 1

**Description**
MMP9

**Timepoint**
Before and 24 hours after intervention

**Method of measurement**
ELISA kit

### 2

**Description**
NIHSS

**Timepoint**
Before intervention, 24 hours, 2 weeks, 1 month and 3 months after intervention

**Method of measurement**
Standard scale

## Secondary outcomes

### 1

**Description**
Side effects

**Timepoint**
24 hours after treatment

**Method of measurement**
Clinic

## Intervention groups

### 1

**Description**
Intervention: 1. Amp N- acetyl- cysteine 100 mg/kg stat in the onset of stroke then 10 mg/kg/hour IV infusion for 10 hours.

**Category**
Treatment - Drugs

### 2

**Description**
Intervention: 2. Tab ASA 325 mg PO daily for 14 days then 80 mg PO daily lifelong

**Category**
Treatment - Drugs

### 3

**Description**
Intervention: 3. Tab plavix 325 mg PO stat then 75 mg daily for 90 days

**Category**
Treatment - Drugs

**4**

**Description**
Control: 2. Tab plavix 325 mg PO stat then 75 mg daily for 90 days
**Category**
Treatment - Drugs

**5**

**Description**
Control: 1. Tab ASA 325 mg PO daily for 14 days then 80 mg PO daily lifelong
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Firoozgar hospital
**Full name of responsible person**
Rezan Ashayeri
**Street address**
Region 6- Valiasr Square- beh Afarin street.
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Zahra Ebrahimi Monazzam
**Street address**
Hemmat highway- near to Mild tower
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Iran University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
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Rezan ashayeri
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**Other areas of specialty/work**
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http://firoozgar.iums.ac.ir/

## Person responsible for scientific inquiries

**Contact**
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Azadeh Eshraghi, Zahra Mirza Asgari
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Assistant professor
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## Person responsible for updating data

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Neurology resident

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**Web page address**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*