

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

**The comparison between levodopa effect and placebo on the improvement of motor function in the patients with stroke in MCA(Middle cerebral artery),randomized.double blind study.**

### Protocol summary

#### Summary

The aim of this study was to evaluate the effectiveness of levodopa in early improvement of motor function outcome after ischemic stroke on the track of middle cerebral artery (MCA). A total of 114 patients with ischemic stroke in the middle cerebral artery (MCA), were placed randomly in to carbidopa-levodopa (Levodopa - C) group to 100 mg daily or placebo group. Both groups received standard treatment for stroke as well. Treatment was started immediately after stroke onset and continued until 21 days later. The Rivermead Mobility Index (RMI) and Barthel's index (BI) of the life quality was used for evaluation of motor deficit at day 22 after treatment. At the end of the third week, with the upper and lower extremity strength differences were compared with each other and at the end of the first month after treatment, the improvement of dysarthria and at the end of the third month after treatment, the presence of spasticity will be review.(at the end of the third week). Inclusion criteria: 1. the patients with ischemic stroke in the MCA territory.2.The absence of another clinical trial simultaneously. Exclusion criteria: 1.major depression, 2.cardiovascular disease 3.tricyclic therapy 4.SSRI therapy 5.dementia.

### General information

#### Acronym

MCA,BI,RMI,CVA.

#### IRCT registration information

IRCT registration number: **IRCT2014042017360N1**

Registration date: **2014-10-03, 1393/07/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2014-10-03, 1393/07/11

#### Registrant information

##### Name

sepideh Zandifar

##### Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1372 8659

##### Email address

zandifar-s@ajums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Ahvaz Jondishapour University of Medical Sciences

#### Expected recruitment start date

2013-04-04, 1392/01/15

#### Expected recruitment end date

2014-03-19, 1392/12/28

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The comparison between levodopa effect and placebo on the improvement of motor function in the patients with stroke in MCA(Middle cerebral artery),randomized.double blind study.

#### Public title

The effect of levodopa on stroke

#### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: the patients with ischemic stroke in the MCA territory. Exclusion criteria: 1.major depression, 2.cardiovascular disease 3.tricyclic therapy 4.SSRI therapy 5.dementia.

## Age

No age limit

## Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: **114**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ahvaz jundishapour university of medical science

##### Street address

Central Building, University City, Golestan,Ahvaz

##### City

ahvaz

##### Postal code

6135715794

#### Approval date

2013-04-05, 1392/01/16

#### Ethics committee reference number

ajums.REC.1392.10

## Health conditions studied

### 1

#### Description of health condition studied

Ischemic stroke

#### ICD-10 code

G46\*

#### ICD-10 code description

Middle cerebral artery syndrome (I66.0+)

## Primary outcomes

### 1

#### Description

motor function

#### Timepoint

three weeks after treatment

#### Method of measurement

Rivermead mobility index and Barthel index

### 2

#### Description

language recovery

#### Timepoint

4 weeks after treatment

#### Method of measurement

NIHSSSI

### 3

#### Description

Comparison between motor recovery of upper and lower limbs

#### Timepoint

3 weeks after treatment

#### Method of measurement

Rivermead mobility index and Barthel index

## Secondary outcomes

### 1

#### Description

Spasticity

#### Timepoint

3 months after treatment

#### Method of measurement

Ashworth modified scale

## Intervention groups

### 1

#### Description

Intervention group: levodopa-c tablet 100/25 mg daily for 21 days in the patients with ischemic stroke in MCA territory.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: placebo tablet 125mr daily for 21 days,in the patients with ischemic stroke in MCA territory.

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Golestan hospital, Neurology Emergency Department

**Full name of responsible person**

Dr. Sepide Zandifar

**Street address**

Golestan Hospital, Golestan ,Ahvaz

**City**

Ahvaz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahvaz jundishapour university of medical science

**Full name of responsible person**

Research Assistant

**Street address**

Ajums central building, University City, Golestan,  
Ahvaz

**City**

Ahvaz

**Grant name****Grant code / Reference number**

u-92017

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz jundishapour university of medical science

**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

**Name of organization / entity**

Ahvaz Jondishapour University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Hasanzade

**Position**

Neurology assistant

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Faculty member

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## Person responsible for updating data

### Contact

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AJUMS

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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*