Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The comparision 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

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Name of organization / entity

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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 comparision 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 strroke 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
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ahvaz
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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
NIHSSSl

3

Description
Comparision 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
Spastisity
Timepoint
3 months after treatment
Method of measurement
Ashworth modified scale

Intervention groups

1

Description
Intervention group: levodopa-c tablet 1oo/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
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Sponsors / Funding sources

1

Sponsor
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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

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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