Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Sep 2026

The effect of lithium in the functional outcome of post ischemic stroke patients

Protocol summary

Summary

Aim of this study is to evaluate the probable effect of lithium as neuroprotective agent on functional outcome of post ischemic stroke patients. Study design: a double blind, single center, randomized clinical trial including intervention and placebo groups Study population: ischemic stroke patients who meet the inclusion and exclusion criteria. The main inclusion criteria are to suffer from acute ischemic stroke (non-embolic) during past 48 hours. The main exclusion criteria are intracerebral hemorrhage or conversion of ischemic stroke to hemorrhagic one, decreased level of consciousness or insult to areas of brain that lead to inability of comprehension of orders, or any medical state or inevitable need to use any drug that have contraindication with consumption of lithium. Sample size: 40 patients in each arm of study (total sample size is 80) Interventions: Intervention group will receive standard treatment of ischemic stroke in addition to lithium carbonate 300mg twice per day. Lithium will be consumed for 30 days Control (placebo) group will receive standard treatment of ischemic stroke in addition to a placebo pill twice per day. Placebo will be consumed for 30 days. Time of intervention: from the first 48 hours of stroke till 30 days later. Outcomes: Primary outcomes are patients' score from NIHSS and Hand section of Fugl-Meyer score at 5th and 30th day of intervention. Secondary outcome is patients' score from Barthel index score at 5th and 30th days of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072210361N1**
Registration date: **2012-11-30, 1391/09/10**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-11-30, 1391/09/10

Registrant information

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Seyed Aidin Sajedi
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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2012-03-29, 1391/01/10

Expected recruitment end date

2012-12-30, 1391/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lithium in the functional outcome of post ischemic stroke patients

Public title

The effect of lithium in the functional outcome of post ischemic stroke patients

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age among 50 to 90; Sufferer from ischemic stroke (ischemic cerebrovascular accident) including class 1, 4 or 5 of TOAST classification system (i.e. all subtypes of ischemic stroke except than embolic stroke with cardiac origin) in the territory of middle cerebral artery; Maximum time passed from stroke should be equal or less than 48 hours; Consent for participation in study (by patient or his/her first degree relative); No-participation in any other clinical trial; Non-menopause females should not be pregnant or lactating mother. Exclusion criteria: Co-existence of intracerebral hemorrhage (subarachnoid or intraparenchymal) or hemorrhagic conversion during hospitalization; Severe loss of consciousness (score greater than 3 from 1b and 1c questions of NIHSS in the time of entering to the study); Wernicke aphasia (pure or as a part of constellation of other symptoms); Organ failures that may interfere with consumption of lithium, including: Acute or chronic kidney disease (Cr> 1.2) Acute or chronic heart failure (EF < 40% or JVP>9cm or history of orthopnea or nocturnal dyspnea) Acute myocardial infarction (during past 3 months or current hospitalization) Pulmonary edema Respiratory distress that demands ventilator Acute or chronic diarrhea that lead to significant dehydration (dryness of mucosal membrane, sunken eyes or Bun/Cr ratio >20) History of thyroid dysfunction or abnormal TSH Inevitable need to thiazide diuretics, potassium sparing diuretics or ACE inhibitors (but not ARB like Losartan) or calcium channel blockers or need to more than 80mg/day of furosemide); Inevitable need to NSAID except than Aspirin; Non-adherence to physiotherapy and ordered rehabilitation.
Age
From **50 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
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 Jundishapur University of Medical Sciences
Street address
Main university building, Medical university campus
City
Ahvaz
Postal code
Approval date
2012-03-03, 1390/12/13
Ethics committee reference number
ETh-403

Health conditions studied

1

Description of health condition studied
Ischemic stroke
ICD-10 code
I63.3
ICD-10 code description
Cerebral infarction due to thrombosis of cerebral arteries

2

Description of health condition studied
The sequelae of Ischemic Stroke
ICD-10 code
I69.3
ICD-10 code description
Sequelae of cerebral infarction

Primary outcomes

1

Description
Functional outcome of stroke patients
Timepoint
in the 5th day of intervention and in the 30th day of intervention
Method of measurement
By using NIHSS and Barthel index score

Secondary outcomes

1

Description
Mortality rate in stroke patients
Timepoint
During 30 days of intervention
Method of measurement
Based on the number of died cases

Intervention groups

1

Description
Intervention group: Lithium carbonate tablet 300 mg twice per day in addition to standard treatment regimen of ASA 80 mg/day, Atorvastatin 20 mg/day and Folic acid 1mg/day and 10 sessions of physiotherapy
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet twice per day in addition to standard treatmet regimen of ASA 80mg/day, Atorvastatin 20mg/day and Folic acid 1mg/day and 10 sessions of physiotherapy
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Dr. Seyed Aidin Sajedi
Street address
Neurology ward, Farvardin Blvd, Golestan hospital
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of research, Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Vice chancelor of research
Street address
Deputy of research Bld, University campus
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of research, Ahvaz Jundishapur 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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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