

**A RANDOMIZED CONTROLLED TRIAL EVALUATING
ELECTROACUPUNCTURE, ACUPOINT INJECTION, AND
ACUPRESSURE MASSAGE FOR MOTOR AND
SWALLOWING REHABILITATION IN PATIENTS WITH
POST-ACUTE ISCHEMIC STROKE**

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Study Site: National Acupuncture Hospital, Vietnam

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Development (NAFOSTED)

Study Protocol

1. Study Title: A randomized controlled trial evaluating Electroacupuncture, Acupoint injection, and Acupressure massage for motor and swallowing rehabilitation in patients with Post-acute ischemic stroke.

2. Background: Cerebral infarction is a major cause of mortality and disability, with hemiparesis and dysphagia being common sequelae. Electroacupuncture, Acupoint injection, and Acupressure massage are widely used in post-stroke rehabilitation. Several studies indicate that acupuncture combined with rehabilitation can improve motor and swallowing functions. However, the comparative efficacy between electro-field acupuncture and electroacupuncture, as well as between Cerebrolysin Acupoint injection and B-complex vitamins Acupoint injection, combined with a baseline treatment of Acupressure massage, requires further evaluation.

3. Objective: To assess the therapeutic efficacy of combined Electroacupuncture (or Electric field acupuncture), Acupoint injection (Cerebrolysin or B-complex vitamins), and acupressure massage in restoring motor function and treating dysphagia in post-acute ischemic stroke patients, while evaluating safety profiles and prognostic factors associated with clinical outcomes.

4. Study Design

A randomized, parallel, 4-group, 2x2 factorial clinical trial with a 1:1:1:1 allocation ratio. Outcome assessors and statistical analysts were blinded to the treatment allocation.

5. Study Population:

5.1. Inclusion Criteria:

- Patients were eligible for inclusion in the study if they met all of the following criteria: Aged 18 years or older, regardless of sex and occupation.
- Diagnosed with post-acute ischemic stroke.
- Stabilized cardiovascular, respiratory, and neurological conditions, as well as vital signs following the acute phase.
- Hemiplegia/Hemiparesis (motor deficit on one side of the body).
- Fully conscious and capable of cooperating with clinicians, with a Mini-Mental State Examination (MMSE) score ≥ 20 .

- Presence of dysphagia, confirmed by a Mann Assessment of Swallowing Ability (MASA) score ≤ 177 .
- National Institutes of Health Stroke Scale (NIHSS) score ≥ 5 .
- Clinical diagnosis of ischemic stroke confirmed by brain magnetic resonance imaging (MRI) showing ischemic lesions.
- Patients and/or their legal representatives voluntarily provided written informed consent to participate in the study.

5.2. Exclusion Criteria:

- Cerebral venous infarction, hemorrhagic transformation of cerebral infarction.
- Stage 3–4 heart failure, cerebral vascular malformations, cerebral air embolism, chronic obstructive pulmonary disease (COPD).
- Respiratory failure requiring endotracheal intubation, impaired consciousness.
- Concurrent systemic or neuropsychiatric conditions: tuberculosis, psychiatric disorders, HIV/AIDS, epilepsy, esophageal stricture, pyloric stenosis.
- Non-cooperative patients, participants who fail to complete the full course of treatment, or patients whose clinical symptoms progressively worsen to a life-threatening level during the study.

6. Interventions:

Participants are allocated to one of four groups:

- (1) Electro-field acupuncture + Cerebrolysin Acupoint injection + Acupressure massage;
- (2) Electro-field acupuncture + B-complex vitamins Acupoint injection + Acupressure massage;
- (3) Electroacupuncture + Cerebrolysin Acupoint injection + Acupressure massage;
- (4) Electroacupuncture + B-complex vitamins Acupoint injection + Acupressure massage.

The planned treatment course is 30 days.

7.Outcomes:

Outcomes include motor function evaluated by the Manual Muscle Testing (MMT), Ashworth scale, NIHSS, Barthel Index, modified Rankin Scale (mRS), Orgogozo scale, and Fugl-Meyer Assessment (FMA); swallowing function evaluated by the Mann Assessment of Swallowing Ability (MASA) and the Gugging Swallowing Screen (GUSS);

Assessing the recovery of neuronal plasticity by quantifying cAMP, cGMP, and BDNF molecules in plasma; paraclinical indicators including electromyography (EMG), electroencephalography (EEG), rheoencephalography (REG), electrocardiography (ECG), hematological and biochemical tests, liver and renal function tests, urinalysis, and vital signs; alongside the recording of any adverse events.

8. Sample Size:

440 patients, with 110 patients per group.

9. Study Site:

National Hospital of Acupuncture, Vietnam.

10. Study Duration:

From December 2026 to December 2028.