

# Combined treatment of patients with stroke-type neurosyphilis

<b>Submission date</b> 17/06/2026	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/07/2026	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/07/2026	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Public, Scientific, Principal investigator

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## Additional identifiers

## Study information

**Scientific Title**  
Efficacy of hyperbaric oxygen therapy combined with ultrasound–neuromuscular electrical stimulation and traditional Chinese medicine acupuncture in patients with stroke-type neurosyphilis

**Study objectives**

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 31/12/2021, Fifth People's Hospital of Suzhou ethics board (No. 10 Guangqian Road, Xiangcheng District, Suzhou, 215131, China; +86 (0)512-87806050; 17431664@qq.com), ref: SZWY20230913

**Primary study design**

Interventional

**Allocation**

Randomized controlled trial

**Masking**

Blinded (masking used)

**Control**

Active

**Assignment**

Parallel

**Purpose**

Treatment

**Study type(s)****Health condition(s) or problem(s) studied**

Stroke-type neurosyphilis

**Interventions**

Patients were randomised 1:1 into the experimental group or the control group using a computer-generated random number table.

Control arm (standard care):

Participants receive standard neurosyphilis care, including:

1. Antibiotic therapy with intravenous aqueous crystalline penicillin G (18–24 million units/day) for 14 days, followed by intramuscular benzathine penicillin G (2.4 million units) weekly for 3 weeks (ceftriaxone 2 g/day intravenously for 14 days is substituted for penicillin-allergic patients)
2. Secondary prevention with aspirin (100 mg/day) or clopidogrel (75 mg/day if intolerant), plus atorvastatin (20 mg/day)
3. Routine rehabilitation consisting of 45 minutes of supervised physical therapy and occupational therapy daily, 5 days per week, plus 45 minutes of home-based therapy with remote monitoring.

Experimental arm:

Participants receive all standard care interventions described above, plus three additional modalities administered concurrently, 5 days per week for 28 days (with 2 days of rest per week):

1. Hyperbaric oxygen (HBO) therapy

2. Transcranial ultrasound–neuromuscular electrical stimulation (TUS-NMES), delivered for 30 minutes once daily, with three ultrasound transducers positioned bilaterally above the zygomatic arches and at the lesion site (60% duty cycle, 0.54 W output power), and neuromuscular electrical stimulation applied through self-adhesive electrodes on affected limbs (pulse width 100  $\mu$ s, frequency 300 Hz)

3. Traditional Chinese medicine acupuncture, performed by licensed practitioners with  $\geq 5$  years' experience, using stainless steel needles (0.25  $\times$  40 mm) inserted at Baihui (GV20, obliquely 15–20 mm), Yintang (EX-HN3, transversely 10–15 mm), and the 'Ningxin' region (1 cm lateral to the midline between GV20 and GV24, bilaterally, perpendicular 10–15 mm), with Deqi sensation elicited, needles retained for 30 minutes with manual manipulation every 10 minutes, once daily.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

1. Neurological recovery measured using the National Institutes of Health Stroke Scale (NIHSS) at 28 days

2. Functional independence measured using the Barthel Index of Activities of Daily Living at 28 days

## **Key secondary outcome(s)**

## **Completion date**

30/06/2024

## **Eligibility**

### **Key inclusion criteria**

1. Positive serum and cerebrospinal fluid (CSF) *Treponema pallidum* particle agglutination
2. CSF white blood cell count  $>5/\mu$ L or elevated protein ( $>0.45$  g/L)
3. Imaging-confirmed cerebral infarction (computed tomography [CT] or magnetic resonance imaging [MRI])
4. Clinical presentation consistent with acute stroke (hemiparesis, aphasia, etc). All participants had neurological deficits with a National Institutes of Health Stroke Scale (NIHSS) score  $\geq 5$ .

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 Years

### **Upper age limit**

75 Years

### **Sex**

All

## **Total final enrolment**

209

## **Key exclusion criteria**

1. Comorbid major neurological disorders
2. Contraindications to HBO therapy, TUS-NMES or acupuncture
3. Pregnancy or breastfeeding
4. Inability to comply with rehabilitation

## **Date of first enrolment**

01/03/2022

## **Date of final enrolment**

30/06/2024

## **Locations**

### **Countries of recruitment**

China

## **Sponsor information**

### **Organisation**

The Fifth People's Hospital of Suzhou

### **ROR**

<https://ror.org/05jy72h47>

## **Funder(s)**

### **Funder type**

### **Funder Name**

The Fifth People's Hospital of Suzhou

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not expected to be made available