ISRCTN82897356 https://doi.org/10.1186/ISRCTN82897356

Combined treatment of patients with stroke-type neurosyphilis

Submission date	Recruitment status	[_] Prospectively registered
17/06/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/07/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/07/2026	Infections and Infestations	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Minzhi Wu

Contact details
No. 10 Guangqian Road, Xiangcheng District
Suzhou
China
215131
+86 (0)15150187616
wuminzhi1202025021@126.com

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 μs, frequency 300 Hz)
3. Traditional Chinese medicine acupuncture, performed by licensed practitioners with ≥5 years' experience, using stainless steel needles (0.25 × 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/μL 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 ≥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