ISRCTN15236545 https://doi.org/10.1186/ISRCTN15236545

Different treatment methods for early disorders of consciousness

Submission date	Recruitment status	[ ] Prospectively registered
01/06/2026	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/06/2026	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/06/2026	Mental and Behavioural Disorders	[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 Long Zhao

Contact details
The Second Hospital of Hebei Medical University
Shijiazhuang
China
050000
+86 (0)311-87046901
zhaoll2658zz@126.com

Additional identifiers

Study information

Scientific Title
Treatment of early consciousness disorders

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/03/2025, The Second Hospital of Hebei Medical University (No. 215, Heping West Road, Xinhua District, Shijiazhuang, 050000, China; -; pub@hb2h.com), ref: 2025-C023

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Early disorders of consciousness

Interventions
The random sequence was generated by SPSS 24.0 software. The patients were divided into 4 groups according to the enrollment ratio of 1:1:1:1. The treatment period is two weeks. A follow-up visit will be conducted one year after the treatment.

1. Transcranial direct current stimulation group (conventional treatment + tDCS): conventional treatment combined with transcranial direct current stimulation (tDCS)
2. Transcranial electrical stimulation group (conventional treatment + tACS): conventional treatment combined with transcranial alternating current stimulation (tACS)
3. Transcranial pulsed electrical stimulation group (conventional treatment + tPCS): conventional treatment combined with transcranial pulse current stimulation (tPCS)
4. Control group (conventional treatment):
4.1. Clinical symptomatic treatment: measures such as dehydration to reduce intracranial pressure, nerve nutrition, anti-infection treatment, nutritional support treatment, and regulation of water, electrolyte, and acid-base balance.
4.2. Regular rehabilitation treatments include:
4.2.1. Lower limb intelligent rehabilitation training
4.2.2. Neuromuscular electrical stimulation
4.2.3. Multiple sensory stimulation
4.2.4. Stimulation of the cerebellar paraflocculus region
4.2.5. Electrical stimulation of the median nerve

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Transcranial electrical stimulation device

Primary outcome(s)
1. The degree of the patient's coma measured using the Glasgow Coma Scale (GCS), comprising three items: eye-opening response (E, up to 4 points), verbal response (V, up to 5 points), and motor response (M, up to 6 points), at within 24 hours after enrollment and after 2 weeks of treatment

2. Neurobehavioral function measured using the Coma Recovery Scale-Revised (CRS-R) , comprising six sub-items including movement, auditory, speech, vision, communication and arousal level, with scores ranging from 0 to 23 points, at within 24 hours after enrollment and after 2 weeks of treatment

3. Electrical activity in the brain measured using electroencephalogram (EEG), comprising 24-channel electrodes placed using the international 10/20 system standard. The grading of consciousness disorders was based on the Synek grading standard of EEG at within 24 hours after enrollment and after 2 weeks of treatment.

4. Pre-attentional processing and sensory memory traces measured using Mismatch Negativity (MMN) (passive Oddball paradigm): the amplitude, latency, and occurrence rate of MMN waves in the frontal-central area at within 24 hours after enrollment and after 2 weeks of treatment

5. Amplitude, latency and occurrence rate of the P3a wave in the superior central area measured using the Medical Event-Related Potential Instrument, Model WJ-1B, at within 24 hours after enrollment and after 2 weeks of treatment

Key secondary outcome(s)
1. Clinical efficacy measured using comprehensive assessment of standardized behavioral scales, neurological functional changes, and functional recovery levels at after 2 weeks of treatment

2. Safety measured using the incidence rates of adverse events such as epileptic seizures, local skin burns, arrhythmias, cardiac arrest, hemodynamic changes, decreased oxygen saturation, removal of tracheal intubation or internal tubes, and worsening of the condition in patients at after 2 weeks of treatment

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Patients with consciousness disorders caused by traumatic brain injury, ischemic hypoxic encephalopathy and cerebrovascular diseases
2. All are first-time cases, with a disease course within 28 days
3. Age between 18 and 80 years old
4. The patients' families are informed, voluntarily participate and sign the informed consent form

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients with critical condition and unstable vital signs/unstable mental state (showing signs of spontaneous recovery or deterioration within 1 week)
2. Patients with severe arrhythmia or those with implanted cardiac pacemakers
3. Patients with metal objects in the brain
4. Patients with active intracranial hemorrhage
5. Patients with a history of epilepsy or a family history of epilepsy
6. Patients with skull defects at the stimulation site, those who have undergone skull metal material repair, or those with local infection

Date of first enrolment
01/04/2025

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
China

Sponsor information

Organisation
Second Hospital of Hebei Medical University

ROR
https://ror.org/015ycqv20

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available