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Can ear acupressure help people with severe liver disease sleep better?

Submission date 17/11/2025	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 19/11/2025	**Overall study status** Completed	
Last Edited 18/11/2025	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

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Study information

Scientific Title
Auricular acupressure for insomnia in patients with decompensated hepatitis B-related liver cirrhosis

Study objectives

This study is conducted to evaluate the efficacy and safety of auricular acupressure for insomnia in patients with decompensated hepatitis B-related liver cirrhosis (DHBV-LC). Our aim was to provide evidence-based support for insomnia management in this population.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/12/2023, Ethics Committee of Beijing You'an Hospital Affiliated to Capital Medical University (No. 8, Xitoutiao, You'anmenwai, Fengtai District, Beijing, 100069, China; +86 01083997028; youanlunli@126.com), ref: JYKLY[2023]343

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Treatment of insomnia in patients with decompensated hepatitis B-related liver cirrhosis

Interventions
Randomization and Blinding
Block randomization with a block size of 4 was generated using a computer-based random number table. The randomization scheme was prepared by an independent statistician and sealed in opaque envelopes. After enrollment, the research nurse opened the envelope corresponding to the patient’s sequence number to determine group allocation. Although the application of auricular acupressure beads makes blinding of patients and treating clinicians unfeasible, outcome assessors and data analysts remained blinded to group allocation throughout the study.

Interventions
The control group received standard therapy based on the Chinese Guideline for the Diagnosis and Treatment of Insomnia in Adults, including sleep hygiene education and psychological counseling. Sleep hygiene education emphasized maintaining a regular sleep-wake schedule; avoiding stimulants such as coffee, strong tea, tobacco, and alcohol before bedtime; refraining from vigorous exercise and heavy meals in the evening; creating a comfortable sleep

environment (temperature 18–22°C, humidity 50%–60%); and practicing relaxation techniques before sleep. Psychological counseling focused on helping patients develop realistic expectations regarding sleep and reducing excessive preoccupation with insomnia.
The intervention group received auricular acupressure in addition to standard therapy. Acupoints were selected with reference to the WHO Standard Acupuncture Point Locations and preceding research, including Shenmen (HT7), Heart, Spleen, Sympathetic, and Subcortex. The procedure was as follows: after routine disinfection of the auricle with 75% alcohol, vaccaria seeds (Semen Vaccariae) were affixed to the designated acupoints. According to the midnight-noon ebb-flow theory ("Zi Wu Liu Zhu" in Chinese) of traditional Chinese medicine, acupressure was performed between 9:00 a.m. and 11:00 a.m. (Spleen meridian peak) and 11:00–13:00 p.m. (Heart meridian peak). Each acupoint was pressed for 30–60 seconds until the patient experienced sensations of soreness, numbness, distension, or mild warmth. Patients were instructed to press the seeds five times daily. Treatment was administered for 5 consecutive days each week, followed by a 2-day rest, constituting one treatment cycle. A total of 4 cycles (4 weeks) were completed.

Intervention Type
Other

Primary outcome(s)
1. Sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of hypnotic medications, and daytime dysfunction measured using Pittsburgh Sleep Quality Index (PSQI) at baseline (within 24 hours before enrolment), week 2, and week 4 (end of treatment)

Key secondary outcome(s)
1. Insomnia severity measured using Insomnia Severity Index (ISI) at baseline(within 24 hours before enrollment), week 2, and week 4 (end of treatment)

2. Irritability with insomnia, frequent dreaming or easy awakening, palpitations with poor memory, dizziness, mental fatigue, and poor appetite with abdominal distension measured using traditional Chinese medicine (TCM) syndrome score at baseline(within 24 hours before enrollment), week 2, and week 4 (end of treatment)

Completion date
30/07/2024

Eligibility

Key inclusion criteria
1. Age between 18 and 80 years
2. Fulfillment of both the diagnostic criteria for insomnia and decompensated cirrhosis: the diagnostic criteria for insomnia included difficulty initiating sleep (sleep latency >30 min), difficulty maintaining sleep (≥2 awakenings per night), early morning awakening, reduced total sleep duration (usually <6.5 h), and poor subjective sleep quality, accompanied by daytime functional impairment. The presence of liver cirrhosis complicated by portal hypertension-related events such as ascites, variceal hemorrhage, or hepatic encephalopathy
3. Pittsburgh Sleep Quality Index (PSQI) score ≥7
4. No insomnia-related treatment within the past month
5. Voluntary participation with signed informed consent

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Secondary insomnia attributable to other causes (e.g. pain, dyspnea)
2. Auricular skin damage, ulceration, or other conditions precluding acupoint intervention
3. History of life-threatening comorbidities such as acute myocardial infarction, stroke, or malignancy; severe psychiatric or psychological disorders
4. Allergy-prone individuals or those with hypersensitivity to study materials; pregnancy or lactation
5. Participation in another clinical trial within the previous three months

Date of first enrolment
16/05/2023

Date of final enrolment
28/06/2024

Locations

Countries of recruitment
China

Sponsor information

Organisation
Beijing You'an Hospital Affiliated to Capital Medical University

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