ISRCTN12585433 https://doi.org/10.1186/ISRCTN12585433

# The effect of acupuncture compared with sham acupuncture and estazolam in primary insomnia

**Submission date**
24/01/2010

**Registration date**
10/03/2010

**Last Edited**
29/10/2013

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
02

## Study information

**Scientific Title**
A single-blind, randomised, sham controlled study of acupuncture in improving daytime functioning of patients suffering from primary insomnia compared with sham acupuncture and estazolam

## Acronym
EAPI

## Study objectives
Patients suffering from long time of insomnia always complain of daytime impairments such as sleepiness, fatigue, alertness, anxiety, worrying, and quality of life, etc., and daytime deficits would presumably have a more negative impact on quality of life. Studies have mainly reported treatment effects of the nocturnal aspects of insomnia, so sufficient attention to daytime functions is needed. Hypnotics are by far the most common treatment offered for insomnia. More or less hypnotics may change the normal structure of sleep which causes worse daytime impairment. Comparatively acupuncture has the advantages of fewer side effects than hypnotics. Studies have shown its significant improvements in nocturnal aspects of insomnia, so it may be also effective in improving daytime functioning as well.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Medical Ethical Committee of the Beijing TCM Hospital approved on the 25th August 2009

## Primary study design
Interventional

## Study design
Single centre single-blind randomised sham-controlled study

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Primary insomnia

## Interventions
This is a six-week, single-blind, randomised, sham-controlled study. A total of 150 untreated patients with primary insomnia will be recruited. Under single-blind conditions, patients will be randomly assigned to one of the three groups:

Group A:
Active acupuncture with estazolam placebo tablet for six weeks. Active acupuncture is conducted by stimulating 5 acupoints: Shen-Ting (DU-24), Si-Shen-Cong (EX-HN1), San-Yin-Jiao (SP-6), Shen-Men (HT-7) and Bai-Hui (DU-20) for 30 minutes every other day. Stainless steel needles of 0.35 mm diameter are inserted at a depth of 10 mm obliquely into Bai-Hui (Du-20) Shen-Ting (DU-24) and Si-Shen-Cong (EX-HN1), 10 mm straightly into San-Yin-Jiao (SP-6) and 5 mm straightly into Shen-Men (HT-7). In the day without acupuncture intervention one estazolam placebo tablet should be taken before sleep.

Group B:
Estazolam combined with sham acupuncture for six weeks. Sham acupuncture is conducted by stimulating 4 acupoints every other day: Bi-Nao (LI-14), Shou-San-li (LI-10), Yu-Ji (LU-10) and Feng-Shi (GB-31). Stainless steel needles of 0.35 mm diameter are inserted straightly at a depth of 10 mm into the four points. According to traditional Chinese medicine theory, these four

acupoints have no effect for insomnia. Estazolam dose is given 1 mg in the day without acupuncture intervention before sleep.

Group C:
Sham acupuncture with estazolam placebo tablet for six weeks. Sham acupuncture is conducted as the group B. In the day without acupuncture one estazolam placebo tablet should be taken before sleep.

The reason for taking the invention every other day is for the convenience of the patients and avoiding addiction of estazolam.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
1. Sleepiness measured using the Epworth Sleepiness Scale. Assessments will be conducted at baseline and at day 7, 14, 28, 42 and 2 months follow-up.
2. Sleep diary assessments will be conducted every day until 2 months follow-up

### Key secondary outcome(s)
1. Changes in the Pittsburgh Sleep Quality Index (PSQI). Assessments will be conducted at baseline and at day 28, 42 and 2 months follow-up.
2. Changes in the 36-item Short Form Health Survey (SF-36) scores. Assessments will be conducted at baseline and at day 28, 42 and 2 months follow-up.

### Completion date
01/12/2010

## Eligibility

### Key inclusion criteria
1. Either gender aged 25 - 75 years
2. Have primary insomnia diagnosed from International Classification of Diseases, 10th Edition (ICD-10)
3. Patients with insomnia persistent for 4 weeks or longer before the start of observation period
4. Have not yet received any psychoactive medications
5. Patients who submit written informed consent for study entry
6. Able to take part in the entire treatment and data collection procedure

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Diagnosis of depression, anxiety or schizophrenia
2. Diagnosis of serious disease of heart, brain, kidney or liver
3. History of sleep apnoea (temporary cessation of breathing during sleep)
4. Suffering from insomnia less than 4 weeks
5. Treatment with investigational drugs in past six months
6. Ever received acupuncture against insomnia, or during the last year received acupuncture for any indication

### Date of first enrolment
01/08/2009

### Date of final enrolment
01/12/2010

## Locations

### Countries of recruitment
China

### Study participating centre
**Acupuncture Department of Beijing TCM Hospital**
Beijing
China
100011

## Sponsor information

### Organisation
Beijing Hospital of Traditional Chinese Medicine (China)

### ROR
https://ror.org/057vq6e26

## Funder(s)

### Funder type
Government

**Funder Name**
Beijing Administration Bureau of Traditional Chinese Medicine (China)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2013 | | Yes | No |