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

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

Submission date	Recruitment status	[ ] Prospectively registered
24/01/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/10/2013	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jing Guo

Contact details
Acupuncture Department of Beijing TCM Hospital
Meishuguanhoujie Road 23
Beijing
China
100011
+86 (0)10 5217 6910
guojing_2002@163.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/08/2009

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

Age group
Adult

Sex
Both

Target number of participants
150

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)

Sponsor details
c/o Jing Guo
Acupuncture Department
Meishuguanhoujie Road 23
Beijing
China
100011
+86 (0)10 5217 6910
guojing_2002@163.com

Sponsor type
Hospital/treatment centre

Website
http://www.bjzhongyi.com/

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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