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Multicenter randomized controlled clinical trial of Harmonizing the Liver and Spleen in the treatment of Primary Insomnia

Submission date
26/04/2014

Recruitment status
No longer recruiting

Registration date
15/05/2014

Overall study status
Completed

Last Edited
04/02/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people suffer from trouble with sleeping because of social, hormonal and behavioral changes. Hypnotics are the most common treatment for insomnia. More or less hypnotics may change the normal structure of sleep, which causes worse daytime impairment. Chinese herbs have fewer side effects than hypnotics. We will evaluate the effectiveness of Chinese herbs to improve the treatment of patients with insomnia.

Who can participate?
Any patient aged 18 to 65 years who has suspected insomnia within the recruited sites will be included in the study.

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive Chinese herb granules and the group will get placebo (dummy) granules. All groups will be measured at the start of the study, after 4 weeks of treatment, after 8 weeks of treatment, just before both groups get one final treatment booster session, and again after 1 month to see if the treatment is effective in the long term.

What are the possible benefits and risks of participating?
Possible benefits for participants are deeper and longer sleep, and improvements of daily functioning that may have been affected by long-term sleep problems, like social functioning. We do not foresee any additional risks to patients in either group of the study.

Where is the study run from?
The study is set up and run by Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, Beijing University of Chinese Medicine Dongfang Hospital and Beijing University of Chinese Medicine Dongzhimen Hospital.

When is the study starting and how long is it expected to run for?
March 2014 to September 2016

Who is funding the study?
Beijing Municipal Science & Technology Commission (China)

Who is the main contact?
Prof Qing-Quan Liu, Chief Investigator
Dr Xue-Qi Zhu ,Trial Coordinator (zhuxueqi615@hotmail.com)

Contact information

Type(s)
Scientific

Contact name
Prof Qing-Quan Liu

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Additional identifiers

Protocol serial number
Z13110200680000

Study information

Scientific Title
A multi-center double-blind, randomized, placebo-controlled study to test the clinical efficacy and safety of harmonizing the liver and spleen in the treatment of primary insomnia

Acronym
HLSPI

Study objectives
To evaluate the efficacy of Chaihuguizhiganjiang-suanzaoren decoction granules in patients with primary insomnia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Beijing Hospital of Traditional Chinese Medicine; 03/07/2014

Primary study design
Interventional

Study design
Multi-center double-blind randomized controlled trial

Study type(s)
Treatment

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

Interventions
The subjects were treated once daily for 8 weeks with herb or placebo granules.

The experimental intervention is chaihuguizhiganjiang-suanzaoren decoction granules, based on 13 TCM herbs/products.

The control intervention is placebo granules, concluded 5% herbal decoction and 95% saccharose, and is similar to the experimental granules in the aspects of color, taste, smell and package.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Sleepiness measured using the Pittsburgh sleep quality index (PSQI). Assessments will be measured at baseline, post-treatment evaluation and the 12-week follow-up evaluations.

Key secondary outcome(s)
1. Changes in the Insomnia Severity Index (ISI). Assessments will be conducted at baseline, post-treatment evaluation and the 12-week follow-up evaluations.
2. Sleep efficiency (SE) from sleep diary will be conducted every day until 12-week follow-up.
3. Changes in the 36-item Short Form Health Survey (SF-36) scores. Assessments will be conducted at baseline, post-treatment evaluation and the 12-week follow-up evaluations.
4. A safety evaluation of the intervention.

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Men or women aged 18 to 65 years
2. Primary insomnia diagnosed from The Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV)
3. Syndromes of spleen deficient and liver heat according to the traditional Chinese medicine clinical trial guiding principles for the treatment of insomnia.
4. Sleep difficulties lasting 1 month or longer, complaint of poor sleep (difficulty initiating and /or maintaining sleep, early morning awakening, or non-restorative sleep)

5. Not to receive another treatment during the clinical trial period
6. Written and informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Diagnosis of secondary insomnia
2. The score of Self-Rating Anxiety Scale (SAS) greater than 60 or the score of Self-Rating Depression Scale (SDS) greater than 63
3. Possible significant mental (e.g. depression) or physical health problems (e.g. cardiovascular disease)
4. A primary diagnosis of alcohol or substance dependency
5. A learning disability
6. Women in pregnancy and lactation or without contraception

Date of first enrolment
01/10/2013

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University
Beijing
China
100010

Sponsor information

Organisation
Beijing Municipal Science & Technology Commission (China)

ROR
https://ror.org/034k14f91

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Science & Technology Commission (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?
Protocol article	protocol	02/02/2016		Yes	No