

6. Nervous System Diseases (including Alzheimer's Disease)**Reference**

Aizawa R, Kanbayashi T, Saito Y, et al. Effects of yoku-kan-san-ka-chimpi-hange on the sleep of normal healthy adult subjects. *Psychiatry and Clinical Neurosciences* 2002; 56: 303-4 CENTRAL ID: CN-00444122, Pubmed ID: 12047606, Ichushi Web ID: 2003024669

1. Objectives

To evaluate the efficacy of yokukansankachimpihange (抑肝散加陳皮半夏) for sleep disorders.

2. Design

Randomized cross-over controlled trial (RCT-cross over).

3. Setting

Not mentioned (probably the Akita Red Cross Hospital), Japan.

4. Participants

Of 20 normal healthy men receiving yokukansankachimpihange before the start of the study, 7 with sleep disorders favorably affected were selected for the study.

5. Intervention

Arm 1: oral administration of yokukansankachimpihange (抑肝散加陳皮半夏) extract (manufacturer, dosage, and dosing frequency unknown) for 3 days followed by 1-week withdrawal and then by oral administration of anchusan (安中散) extract for 3 days.

Arm 2: oral administration of anchusan (安中散) extract (manufacturer, dosage, and dosing frequency unknown) for 3 days followed by 1-week withdrawal and then by oral administration of yokukansankachimpihange (抑肝散加陳皮半夏) extract product for 3 days.

(The grouping method for the 7 subjects is not indicated).

6. Main outcome measures

Sleep time, sleep latency, sleep depth, and rapid eye movement (REM) sleep time.

7. Main results

Total sleep time was significantly prolonged in arm 1 (438±13 min vs 371±19 min in arm 2).

8. Conclusions

Yokukansankachimpihange increases sleep time.

9. From Kampo medicine perspective

Seven subjects responding to yokukansankachimpihange were selected for the double-blind study.

10. Safety assessment in the article

No adverse drug reactions occurred in either group.

11. Abstractor's comments

This study, which investigated the efficacy of yokukansankachimpihange for sleep in a double-blind RCT, provides high-quality evidence. However, giving participants yokukansankachimpihange as pretreatment and using anchusan (which has a similar taste) as the control may have compromised blinding. Nevertheless, the research content is advantageous in that it involved objective evaluation of sleep using all-night polysomnography. Investigation with a larger sample size is expected.

12. Abstractor and date

Goto H, 15 June 2007, 1 April 2008, 1 June 2010.