

19. Injury, Poisoning, and Postoperative Pain**Reference**

Nimura T, Yamada S, Ohwaki T, et al. Evaluation of the efficacy of Kampo therapy in patients with heat illness requiring hospitalization*. *Kampo Igaku (Kampo Medicine)* 2014; 38; 178-81 (in Japanese). Ichushi Web ID: 2015015844

1. Objectives

To evaluate the efficacy of Kampo therapy in patients with heat illness requiring hospitalization.

2. Design

Randomized controlled trial (RCT). However, the attending physicians were randomly assigned.

3. Setting

A department of internal medicine in a general hospital in Aichi Prefecture, Japan.

4. Participants

Thirty-four patients who were admitted to the hospital due to hyperthermia during the summer seasons (July to September) from 20xx to 20xx (2 years).

Hyperthermia was diagnosed and its severity was graded according to the severity classification (Classes I to III) of the Japanese Congress on Neurological Emergencies.

5. Intervention

Arm 1: Kampo arm (fluid replacement + Kampo medicine). Four physicians who routinely prescribe Kampo medicines were randomly assigned to this arm. (n=20)

Arm 2: Non-Kampo arm. Only fluid replacement was administered. Four physicians who do not routinely prescribe Kampo medicines were randomly assigned to this arm. (n=14)

6. Main outcome measures

Number of hospitalization days.

7. Main results

No inter-arm differences in age, sex, presence or absence of primary disease, laboratory data on admission, or severity of hyperthermia were found. Kampo medicines used in the Kampo arm were hochuekkito (n=17), rikkunshito (n=1), daikenchuto (n=1), and yokukansan (n=1). The hospitalization period was significantly shorter in the Kampo arm (5.1±3.7 days) than in the non-Kampo arm (15.8±16.1 days) for all hyperthermia severity Classes I to III ($P<0.05$) and for severity Class III (4.9±3.6 days in the Kampo arm vs. 20.5±18.5 days in the non-Kampo arm; $P<0.05$).

8. Conclusions

Kampo medicines shorten the period of hospitalization for hyperthermia.

9. From Kampo medicine perspective

No differences were found in effects of four Kampo medicines used in the study: hochuekkito, rikkunshito, daikenchuto, and yokukansan. According to the article, Kampo medicines (seishoekkito, hochuekkito, rikkunshito, ninjinto, goreisan, and ireito) had previously been used for treating summer fatigue and heat exhaustion, but not for hyperthermia requiring hospitalization.

10. Safety assessment in the article

One subject in each arm died in the study, but these deaths had no causal relationship with Kampo medicines.

11. Abstractor's comments

This study is important because the efficacy of Kampo medicines in subjects with hyperthermia requiring hospitalization was evaluated in an RCT. Since this article is a short report, the study methods and the results were not fully described. The study design was an RCT; however, the prescribing physicians (Arm 1: physicians who routinely prescribe Kampo medicines, Arm 2: physicians who do not routinely prescribe Kampo medicines) were randomly assigned to each study arm. Therefore, neither the physicians nor the subjects were blinded. As in the usual RCT design, which would be preferable, just one Kampo medicine was used for evaluation and comparison between the Kampo and placebo control arms. The development of future studies is anticipated.

12. Abstractor and date

Tsuruoka K, 31 March 2017.