

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

Takamura M, Effectiveness of Kampo extract preparations for the treatment of heat illness.\* *Kampo to Saishinchiryō (Kampo & the Newest Therapy)* 2014; 23: 121-4 (in Japanese).

**1. Objectives**

To evaluate the effect of Kampo extract preparations as an adjunct to the standard therapy to shorten the symptom resolution time in patients with heat illness.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One clinic, Japan.

**4. Participants**

Eleven male patients with heat illness assessed as Class II (moderate) in severity, occurring at manufacturing sites of companies with around 3000 employees (including exterior and interior sites) between June and September in 2010 and 2011, who were able to drink water.

**5. Intervention**

For Kampo medicines, one packet (2.5 g) of TSUMURA Shyakuyakukanzoto (芍薬甘草湯) Extract Granules was used as a single dose for subjects with muscle cramp or myalgia. Otherwise, one packet (3.0 g) of TSUMURA Byakkokaninjinto (白虎加人參湯) Extract Granules was used as a single dose.

Arm 1: Cooling + oral rehydration solution (Otsuka OS-1) + saline infusion + Kampo extract preparation (n=5).

Arm 2: Cooling + oral rehydration solution (Otsuka OS-1) + saline infusion (n=6).

**6. Main outcome measures**

Time from onset to symptom resolution.

**7. Main results**

Symptoms in all subjects improved after treatment. Time to symptom resolution was significantly shorter in the Kampo arm (48.0±13.5 minutes vs 80.8±21.8 minutes;  $P=0.017$ ). No significant difference in age, blood pressure, body temperature, fluid replacement, or total water requirement was found between the arms.

**8. Conclusions**

Adding shyakuyakukanzoto or byakkokaninjinto extract to the standard rehydration therapy (of cooling and salt and water supplementation) may shorten the time to symptom improvement in patients with heat illness.

**9. From Kampo medicine perspective**

In Kampo therapy, byakkokaninjinto is believed to be effective for treatment of the following symptoms: *etsu* (暍, summerheat stroke), sweating, feeling hot in the body and thirsty. Shyakuyakukanzoto is used for treatment of myalgia and muscle stiffening symptoms.

**10. Safety assessment in the article**

No adverse events were noted.

**11. Abstractor's comments**

This is an interesting clinical study because the addition of one packet of Kampo extract preparations to the standard therapy for heat illness significantly shortened the time to symptom resolution by 30 minutes. On the other hand, since the number of subjects was small and two types of Kampo medicines were used in the study, the results in this study should be reviewed in the future. Meanwhile, the author's efforts to obtain randomized data from a population requiring emergency medical attention, which is difficult in actual clinical settings, should be respected. Although each subject's *sho* (証, pattern) was not diagnosed, shyakuyakukanzoto and byakkokaninjinto were appropriate for heat illness. As stated by the author, shortening of the time to symptom resolution in patients with mild to moderate heat illness, which is estimated to affect 30,000 patients annually in Japan, is meaningful from a medical cost standpoint. Further development is anticipated in future studies assessing the efficacy and safety of Kampo medicines added to the standard therapy.

**12. Abstractor and date**

Fujisawa M, 31 March 2017.