#### **Evidence Reports of Kampo Treatment**

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

# 18. Symptoms and Signs

#### Reference

Ohno S, Suzuki T, Asaoka T, et al. Effects of Oriental medicine on lymphoid cells. *Kampo to Meneki-Allergy* (*Kampo and Immunoallergy*) 1995; 9: 78-86 (in Japanese with English abstract). Pubmed ID: 21724872

## 1. Objectives

To evaluate the effect of hochuekkito (補中益気湯) on lymphocytes.

#### 2. Design

Quasi-randomized controlled trial (quasi-RCT).

## 3. Setting

One center: the Second Department of Internal Medicine, Saitama Medical University Hospital, Japan.

# 4. Participants

Thirty people who presented at an Oriental medicine outpatient clinic with fatigue.

# 5. Intervention

Arm 1: TSUMURA Hochuekkito (補中益気湯) Extract Granules group (n=15).

Arm 2: TSUMURA Hachimijiogan (八味地黄丸) Extract Granules group (n=15).

#### 6. Main outcome measures

Changes in leukocyte, neutrophil, and lymphocyte counts; response of lymphocytes to phytohemagglutinin (PHA) and concanavalin A (ConA) stimulation.

# 7. Main results

No changes in leukocyte or neutrophil count were observed. Lymphocyte count increased significantly in arm 1 (P<0.05). Lymphocyte count decreased with PHA and ConA stimulation in arm 2, and, conversely, lymphocyte count (particularly large-granular lymphocyte count) increased with ConA stimulation in arm 1.

## 8. Conclusions

Hachimijiogan and hochuekkito have different effects on the lymphocyte system in vivo.

## 9. From Kampo medicine perspective

None.

## 10. Safety assessment in the article

One participant taking hochuekkito suffered constipation and three taking hachimijiogan suffered stomach discomfort, but no serious adverse effects were observed.

# 11. Abstractor's comments

While the significant increase in lymphocyte count in the hochuekkito group is the starting point for this study, the lymphocyte counts prior to treatment in the control group (hachimijiogan group) were widely scattered, which might explain the lack of any significant difference between the groups (Fig. 6 and Fig. 7). Increasing the number of participants in a future study may reduce between-group differences. Accordingly, it would be better to make the control group a no-treatment group, rather than a hachimijiogan group. Interestingly, the increase in the lymphocyte count (particularly large-granular lymphocyte count) and NK activity in the hochuekkito group suggests hochuekkito has an effect on tumor immune cells. Hopefully the authors will conduct a further study into the question of whether hachimijiogan and hochuekkito have similar activities, with an increased number of participants.

# 12. Abstractor and date

Nakata H, 31 December 2013.