

Evidence Reports of Kampo Treatment

Task Force for Evidence Reports, the Japan Society for Oriental Medicine

Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine.

1. Infections (including Viral Hepatitis)

Reference

Enomoto Y, Hagiwara E, Komatsu S, et al. Pilot quasi-randomized controlled study of herbal medicine hochuekkito as an adjunct to conventional treatment for progressed pulmonary *mycobacterium avium* complex disease. *PLOS ONE* 2014; 9: 1-8. CENTRAL ID: CN- 00998327, Pubmed ID: 25093868

1. Objectives

To evaluate the effectiveness of hochuekkito (補中益気湯) as an adjunct to conventional treatment for progressed refractory pulmonary *Mycobacterium avium* complex (MAC) disease.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

One hospital, Japan.

4. Participants

Eighteen pulmonary MAC disease patients aged 20 years or older who were treated for at least one year but persistently culture-positive, or who were difficult to treat with antibiotics due to drug allergy.

5. Intervention

Prior treatment: Combination of rifampicin, ethambutol, clarithromycin, levofloxacin, kanamycin, and streptomycin or no treatment.

Arm 1: Hochuekkito (補中益気湯) (manufacturer unknown) administered orally 2.5 g b.i.d. or 2.5 g t.i.d. + prior treatment for up to 24 weeks (n=9) (one subject untreated).

Arm 2: Prior treatment (n=9) (one subject untreated).

6. Main outcome measures

Sputum conversion rate at 24 weeks and number of MAC colonies.

Change in shadow size in the lungs at 24 weeks.

Chronic obstructive pulmonary disease assessment test (CAT) scores and serum albumin level, serum C-reactive protein (CRP) level, and erythrocyte sedimentation rate (ESR).

7. Main results

The sputum of all subjects remained positive for bacteria throughout the study. The number of colonies from baseline to 24 weeks remained essentially unchanged in Arm 1 or 2. Chest X-ray revealed improvement or no change in 8 subjects in Arm 1, and 3 subjects in Arm 2, showing that the MAC disease had a significantly more favorable course in the hochuekkito arm. CAT scores and ESR and CRP levels were worsened in most subjects in the two arms, but body weight and serum albumin level tended to increase in Arm 1. Interestingly, body weight increased in all subjects with radiographic improvement and decreased in most subjects with radiographic progression.

8. Conclusions

Although patients in the hochuekkito group had higher baseline ESR level and lower baseline blood albumin level, they showed chest radiographic improvement and increased body weight. Thus hochuekkito is useful as a therapeutic drug for pulmonary MAC disease.

9. From Kampo medicine perspective

Hochuekkito is indicated for patients in poor general condition.

10. Safety assessment in the article

No serious adverse events were noted.

11. Abstractor's comments

This RCT selected study subjects from a group of 155 patients with pulmonary MAC disease. These days, the number of pulmonary MAC disease patients is increasing. Since patients are not always responsive to general treatment, this study treatment seems meaningful. Establishing true outcome measures will improve the quality of evidence in a future RCT. Further development of this research is anticipated.

12. Abstractor and date

Fujisawa M, 31 March 2017.