1. Infections (including Viral Hepatitis)

References

Shijubo N, Nakanishi F. Experience with hochuekkito in the short-course intensified chemotherapy for pulmonary tuberculosis – the reducing effect on hepatic dysfunction occurring as an adverse drug reaction–*. *Kampo Igaku* (*Kampo Medicine*) 1993; 17: 241-3 (in Japanese).

Nakanishi F. Experience with hochuekkito in the short-course intensified chemotherapy for pulmonary tuberculosis*. *Nikkei Medical* 1994; 23 (12): 24-5 (in Japanese).

1. Objectives

To determine the efficacy of hochuekkito (補中益気湯) for reducing hepatic dysfunction and improving digestion and malabsorption in tuberculosis patients undergoing chemotherapy.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital, Japan.

4. Participants

Eighty hospitalized patients with tuberculosis who had no history of liver disease and no hepatic dysfunction on admission.

5. Intervention

Anti-tubercular agents were RFP+INH+SM (EB) for patients who excreted tubercle bacilli and RFP+INH for patients who tested negative for tubercle bacillus excretion and vomicae.

Arm 1: chemotherapy + treatment with TSUMURA Hochuekkito (補中益気湯) Extract Granules 2.5 g t.i.d. between meals (n=40).

Arm 2: chemotherapy alone (n=40).

6. Main outcome measures

Hepatic dysfunction and body weight.

7. Main results

Abnormal glutamic-oxaloacetic transaminase (GOT), glutamic-pyruvic transaminase (GPT), and GOT and/or GPT levels were observed in 10%, 10%, and 13% of patients in arm 1 and 23%, 28%, and 30% in arm 2. Obviously, the occurrence of hepatic dysfunction was decreased in arm 2. The rate of weight gain began to increase at 1 month in arm 1 and at 2 months in arm 2.

8. Conclusions

Coadministration of hochuekkito reduces hepatic dysfunction resulting from RFP/INH-based chemotherapy and stimulates body weight gain, which is an indicator of improved *hiiqikyo* (impaired digestion and absorption), but does not normalize C-reactive protein level or prevent tuberculosis bacillus excretion.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

GOT and GPT levels increased to 200 IU/L or higher and treatment discontinuation was required in 2 patients of arm 1.

11. Abstractor's comments

Nakanishi (1994) adds 16 participants to the paper by Shijubo et al. (1993). Hepatic dysfunction due to anti-tubercular agents increased slightly for the first one to two months of administration, but in most cases it gradually improved even with continued use. However, in some cases, hepatic dysfunction was severely aggravated and required regular monitoring. This RCT provides some interesting outcomes in terms of reducing the occurrence of hepatic dysfunction.

12. Abstractor and date

Fujisawa M, 31 March 2009, 1 June 2010, 31 December 2013.