

**11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases****Reference**

Mizutani Y, Imai S, Watanabe H, et al. Saiko-keishi-to in patients with pulmonary tuberculosis: effect on liver dysfunction. *Donan Igakkaishi (Journal of the Medical Association of South Hokkaido)* 1994; 29: 247-9 (in Japanese).

**1. Objectives**

To evaluate the efficacy of saikokeishito (柴胡桂枝湯) for hepatic dysfunction associated with chemotherapy for pulmonary tuberculosis.

**2. Design**

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

**3. Setting**

Four hospitals, Japan.

**4. Participants**

Thirty-eight patients with pulmonary tuberculosis who received combination chemotherapy containing rifampicin for the first time.

**5. Intervention**

Arm 1: saikokeishito (柴胡桂枝湯) (unknown manufacturer) at a dose of 7.5 g t.i.d. for 8 weeks (n=21).  
Arm 2: no treatment (n=17).

**6. Main outcome measures**

Serum glutamic-oxaloacetic transaminase (GOT) and glutamic-pyruvic transaminase (GPT) levels.

**7. Main results**

Thirty-three patients were included in the analysis. The incidence of abnormal GOT and GPT levels was 27.8% and 38.9% in arm 1, and 6.7% and 20.0% in arm 2, respectively. More patients had abnormal GOT and/or GPT in arm 1 than in arm 2, but the between-arm difference was not significant.

**8. Conclusions**

Saikokeishito is not effective for hepatic dysfunction associated with chemotherapy for pulmonary tuberculosis.

**9. From Kampo medicine perspective**

Mentioned in the discussion section of the reference.

**10. Safety assessment in the article**

Not documented.

**11. Abstractor's comments**

While randomization by the envelope method is often difficult to attain, it is interesting that this clinical trial showed that saikokeishito was ineffective for prevention of hepatic dysfunction, an adverse reaction to chemotherapy for pulmonary tuberculosis. It is desirable to conduct a randomized controlled trial with more patients using an improved randomization scheme.

**12. Abstractor and date**

Okabe T, 21 August 2008, 1 June 2010.