

2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)**Reference**

Ayukawa K, Sato T, Nagase S, et al. Preventive effect of shosaikoto on liver carcinogenesis*. *Rinsho to Kenkyu (Japanese Journal of Clinical and Experimental Medicine)* 1994; 71: 1874–6 (in Japanese). Ichushi Web ID: 1995019997

1. Objectives

To evaluate the preventive effect of shosaikoto (小柴胡湯) on the progression of cirrhosis to liver cancer.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

One university hospital (3rd Department of Internal Medicine, Kyushu University) and 8 other hospitals, Japan.

4. Participants

Ninety-five patients with cirrhosis diagnosed by laparoscopy, liver biopsy, and laboratory examination.

5. Intervention

Randomization based on whether the birth month is odd or even.

Arm 1: administration of TSUMURA Shosaikoto (小柴胡湯) Extract Granules 5.0–7.5 g/day (n=52).

Arm 2: no administration of TSUMURA Shosaikoto (小柴胡湯) Extract Granules (n=43).

6. Main outcome measures

Incidence of liver cancer during the 3-year period, alpha-fetoprotein (AFP) level, and blood biochemistry.

7. Main results

There was no significant difference in 3-year incidence of liver cancer between arms. AFP tended to be lower in arm 1, although not significantly lower. GOT was significantly lower in arm 1 only at weeks 12 and 15.

8. Conclusions

While not significant, the Shosaikoto treatment tends to lower the incidence of liver cancer and AFP.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse events in arm 1 did not occur and adverse events in arm 2 were not mentioned.

11. Abstractor's comments

This study is a sequel of the study by Oka et al. (Oka H, Yamamoto S. Controlled prospective study of prevention of hepatocellular carcinoma of the liver. *Shokakika (Gastroenterology)* 1991; 15: 71-8.) and may have failed to demonstrate significant differences because the follow-up period of 3 years was too short and the doses of TSUMURA Shosaikoto Extract Granules (5.0–7.5 g) were too low. Thereafter, shosaikoto was contraindicated for cirrhosis in principle, further compromising the usefulness of this study.

12. Abstractor and date

Hoshino E, 22 February 2009, 1 June 2010.