1. Infections (including Viral Hepatitis)

Reference

Fukue H, Hagiwara T, Yoshida S, et al. Efficacy of high-dose shosaikoto for HIV infection*. *HIV Kansensha Hassho Yobo, Chiryo ni kansuru Kenkyuhan Heisei 7 Nendo Kenkyu Hokokusho* (*Research Report by the Study Group on Prevention and Treatment of HIV Infection*) 1996: 203–10 (in Japanese).

1. Objectives

To evaluate the efficacy and safety of shosaikoto (小柴胡湯) in the treatment of human immuno-deficiency virus (HIV) infection.

2. Design

Double-blind, randomized controlled trial (DB-RCT).

3. Setting

No study site was specified (authors belonged to the Department of Diagnostic Pathology, Tokyo Medical University; National Institute of Health; Department of Public Health, Yokohama City University; and Division of Theoretical Epidemiology, Department of Epidemiology, Institute of Public Health), Japan.

4. Participants

Nineteen patients with acquired immunodeficiency syndrome (AIDS) related complex or asymptomatic carriers with 200–500 CD4-positive cells/μL.

5. Intervention

Arm 1: TSUMURA Shosaikoto (小柴胡湯) Extract Granules at a dose of 7.5 g t.i.d. for 12 weeks.
Arm 2: placebo.

6. Main outcome measures

Immunology (absolute number of CD4-positive cells, CD4/CD8, and lymphocyte stimulation test), virology (P24 antigen, branched DNA assay), and clinical symptoms.

7. Main results

A total of 15 patients (7 in arm 1 and 8 in arm 2) were included in the analysis. After treatment, no statistically significant between-arm difference was found in the absolute number of CD4-positive cells, CD4/CD8, and results of the lymphocyte stimulation test. Virologically, no analysis could be performed because many patients lacked detectable virus.

8. Conclusions

Shosaikoto may be ineffective for HIV infection.

9. From Kampo medicine perspective

Mentioned in the discussion section of the reference.

10. Safety assessment in the article

In the shosaikoto group, 1 patient was withdrawn from treatment owing to hepatic dysfunction. Two patients in each of the groups had slight gastrointestinal symptoms.

11. Abstractor's comments

This clinical trial suggested that shosaikoto is ineffective for HIV infection. Nonetheless, it is desirable to conduct another trial to overcome the following drawbacks of the present trial as cited by the authors: small sample size and lack of antiviral efficacy evaluation because no virus was detectable.

12. Abstractor and date

Okabe T, 17 September 2008, 1 June 2010.