

14. Genitourinary Tract Disorders (including Climacteric Disorders)**Reference**

Yoshikawa N, Ito H, Sakai T, et al. A prospective controlled study of sairei-to in childhood IgA nephropathy with focal/minimal mesangial proliferation. *Nihon Jinzo Gakkaishi (The Japanese Journal of Nephrology)* 1997; 39: 503-6 (in Japanese with English abstract). CENTRAL ID: CN-00143175, Pubmed ID: 9283216

1. Objectives

To evaluate the efficacy and safety of saireito (柴苓湯) in childhood IgA nephropathy with focal/minimal mesangial proliferation.

2. Design

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

3. Setting

Departments of Health Science of Kobe University School of Medicine, Kidney Center of Kitasato University Hospital, Department of Pediatrics of Hokkaido University, etc. (a total of 29 institutions including 16 university hospitals and 9 departments of pediatrics), Japan.

4. Participants

One hundred and one patients aged 15 or under with newly diagnosed IgA nephropathy with focal/minimal mesangial proliferation.

5. Intervention

Arm 1: administration of TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d. (body weight ≥ 40 kg), 3.0 g b.i.d. (body weight 20–40 kg), or 1.5 g b.i.d. (body weight ≤ 20 kg) for two years (n=50).
Arm 2: no treatment (n=51).

6. Main outcome measures

Daily urinary protein excretion, hematuria in morning urine, and renal function (blood urea nitrogen, serum creatinine, creatinine clearance, etc) at the start and end of treatment.

7. Main results

At the end of the trial, mean daily urinary protein excretion was significantly decreased from the initial 0.39 ± 0.31 g/day to 0.25 ± 0.21 g/day in the 46 patients included for analysis in arm 1 ($P=0.005$), while it remained unchanged in the 48 patients included for analysis in arm 2 (0.41 ± 0.48 g/day vs. 0.43 ± 0.56 g/day). Hematuria in the morning urine was also significantly attenuated after two years of the trial in arm 1 (from 2.3 ± 1.0 to 1.0 ± 1.1) ($P < 0.0001$), but was not decreased in arm 2 (from 2.1 ± 1.1 to 1.8 ± 1.2). Urinary findings became normal in 46% of arm 1 and 10% of arm 2, showing significant difference between arms ($P < 0.001$).

8. Conclusions

Saireito is effective for childhood IgA nephropathy with focal/minimal mesangial proliferation.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse reaction was observed.

11. Abstractor's comments

Although in Japan randomization by the RCT-envelope method tends not to be maintained, the present study suggests the efficacy of saireito for early treatment of childhood IgA nephropathy with focal/minimal mesangial proliferation. It is interesting that urinary findings were normalized in 46% of patients.

12. Abstractor and date

Okabe T, 22 August 2008, 6 January 2010, 1 June 2010, 31 December 2013.