

15. Ante/Post-partum Diseases**Reference**

Takushima Y, Michigami F. Clinical study of Saireito on gestational edema and upper gastrointestinal symptoms. *Igaku to Yakugaku (Japanese Journal of Medicine and Pharmaceutical Science)* 2010; 64: 709–15 (in Japanese). Ichushi Web ID: 2011072703 [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the effectiveness of saireito (柴苓湯) combined with either sojutsu (蒼朮, *Atractylodes Lancea* Rhizome) or byakujutsu (白朮, *Atractylodes* Rhizome) as constituent crude drugs for lower limb edema and functional dyspepsia-like gastrointestinal symptoms.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

One hospital, Japan.

4. Participants

Fifty women in the latter stage of pregnancy with lower limb edema not associated with hypertension requiring drug therapy, and gastrointestinal symptoms such as appetite loss.

5. Intervention

Arm 1: saireito (柴苓湯) extract granules (manufacturer not identified) 3.0 g t.i.d. combined with sojutsu (蒼朮, *Atractylodes Lancea* Rhizome) for 4 weeks (n=25).

Arm 2: saireito (柴苓湯) extract granules (manufacturer not identified) 4.05 g b.i.d. combined with byakujutsu (白朮, *Atractylodes* Rhizome) for 4 weeks (n=25).

6. Main outcome measures

Ankle edema (ankle circumference), plantar edema (plantar circumference), gastrointestinal symptoms (questionnaire).

7. Main results

Ankle circumference began to improve significantly 2 weeks after saireito administration in both arms 1 and 2 ($P<0.05$). Improvement of plantar circumference after 4 weeks was significant in Arm 2 but not in Arm 1. Epigastralgia and bloating after meals at the end of the 4-week period of administration ($P<0.05$), epigastric heat sensation after treatment for 3 weeks ($P<0.01$), heaviness in the stomach after treatment for 3 weeks ($P<0.05$), and upper gastrointestinal symptoms overall (including gastrointestinal symptoms) after treatment for 3 weeks ($P<0.05$) were significantly improved in Arm 2 only.

8. Conclusions

Saireito combined with sojutsu and saireito combined with byakujutsu are both effective for lower limb edema in pregnancy. Of these combinations, only saireito + byakujutsu improve epigastric symptoms significantly.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse effects were observed.

11. Abstractor's comments

This is a quasi-randomized controlled trial in which medications were allocated in order of patient presentation. It is a significant clinical trial that compared the effects of byakujutsu or sojutsu with saireito for lower limb edema and epigastric symptoms in pregnancy. Before-after comparison demonstrated that only saireito combined with byakujutsu is effective for epigastric symptoms. This was probably a reflection of byakujutsu's capacity to promote gastrointestinal function. Therefore, the two different saireito formulae appear to be indicated for different patterns. A further study is recommended for comparison of groups in a randomized trial that includes a placebo group.

12. Abstractor and date

Okabe T, 1 December 2012.