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

Reference

Kaku H, Kumagai S, Onoue H, et al. Objective evaluation of the alleviating effects of goshajinkigan on peripheral neuropathy induced by paclitaxel/carboplatin therapy: A multicenter collaborative study. *Experimental and Therapeutic Medicine* 2012; 3: 60-5. Pubmed ID: 22969845

1. Objectives

To evaluate the efficacy of goshajinkigan (牛車腎気丸) for peripheral neuropathy induced by chemotherapy (paclitaxel and carboplatin) for uterine and ovarian cancer.

2. Design

Randomized controlled trial (RCT).

3. Setting

Obstetrics and gynecology departments at four university hospitals (Iwate Medical University, Tottori University, Kitasato University, and Keio University), Japan.

4. Participants

Twenty-nine patients (20–70 years old) with peripheral neuropathy rated grade 1 or higher under the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) and treated with paclitaxel/carboplatin after uterine or ovarian cancer had been histologically diagnosed.

5. Intervention

Arm 1: oral administration of vitamin B12 (1.5 g/day) and TSUMURA Goshajinkigan (牛車腎気丸) (7.5 g/day) (n=14).

Arm 2: oral administration of vitamin B12 (1.5 g/day) (n=15).

6. Main outcome measures

Visual analogue scale (VAS) evaluation of subjective numbness symptoms at 0, 3, and 6 weeks.

Rating of peripheral neuropathy (movement and sensation) under the NCI-CTCAE at 0, 3, and 6 weeks.

Evaluation of subjective peripheral neuropathy symptoms using the Functional Assessment of Cancer Treatment (FACT)-Taxane questionnaire at 0, 3, and 6 weeks.

Measurement of the current perception threshold (CPT) range in both index fingers at 0, 3, and 6 weeks.

7. Main results

There was no significant difference between groups at 0, 3, or 6 weeks in the VAS score for numbness and FACT-Taxane score for peripheral neuropathy (movement and sensation), or peripheral neuropathy symptoms. Peripheral neuropathy (sensation) was rated grade 3 under the NCI-CTCAE at 6 weeks in 2 patients of arm 2; however, no patient in arm 1 scored grade 3 or higher at 6 weeks. There was no significant difference between groups for the CPT range.

The frequency of abnormal CPT range was significantly lower in arm 1 than arm 2.

8. Conclusions

Goshajinkigan is effective for controlling the advance of peripheral neuropathy induced by paclitaxel/carboplatin.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This multicenter RCT tested whether goshajinkigan in combination with vitamin B12 can improve peripheral neuropathy induced by paclitaxel/carboplatin for gynecologic cancer patients. The study did not find effectiveness of goshajinkigan based on subjective numbness symptoms (VAS) score, NCI-CTCAE grade, or FACT-Taxane score. However, 6 weeks after administration commenced, CTCAE grade deteriorated to 3 in two participants in the vitamin B12-only group and no participant in the vitamin B12 plus goshajinkigan group (arm 1). Additionally, the frequency of abnormal CPT range was significantly lower in arm 1. On those grounds, the authors assert that goshajinkigan is useful for controlling subjective symptoms. Nevertheless, the authors did not observe any positive effect of goshajinkigan, thereby raising the issue of whether goshijinkigan is a suitable drug for controlling subjective symptoms, and whether the 6-week period of administration is appropriate. When conducting a trial such as this, researchers should first elucidate what kinds of Kampo medications are effective and for what periods by carrying out an exploratory study whereby a physician expert in Kampo medical treatment provides appropriate Kampo treatment based on Kampo patterns, and then create study protocols.

12. Abstractor and date

Hoshino E, 31 December 2013.