2. Cancer (Postoperative Cancer Patients, Unspecific Adverse Reactions to Anticancer Agents)

Reference

Konno H, Maruo Y, Baba S, et al. Improvement of host-immunity by adding juzen-taiho-to to the postoperative adjuvant chemotherapy for patients with gastric cancer. *Biotherapy* 1997; 11: 193-9 (in Japanese with English abstract). MOL, MOL-Lib

1. Objectives

To evaluate the effect of juzentaihoto (十全大補湯) in host-immunity in gastric cancer patients undergoing postoperative adjuvant uracil+tegafur (UFT, 300 mg/day).

2. Design

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

3. Setting

One university hospital (Second Department of Surgery, Hamamatsu University School of Medicine) and two other hospitals, Japan.

4. Participants

Twenty-three patients who underwent macroscopic curative resection of gastric cancer (stage I-III).

5. Intervention

Arm 1: UFT 300 mg/day + TSUMURA Juzentaihoto (十全大補湯) Extract Granules 2.5 g t.i.d. from 2 to 14 weeks after surgery (n=11).

Arm 2: UFT 300 mg/day alone (n=12).

6. Main outcome measures

Hematology (hemoglobin, white blood cell count, lymphocyte count, suppressor T cell %, cytotoxic T cell %): 1, 3, 6, and 12 months after the start of treatment.

Scores of subjective symptoms (performance status [PS], anorexia, general malaise): once a month.

7. Main results

There were no between-arm differences in hemoglobin level, white blood cell count, and lymphocyte count. Suppressor T cells (%) tended to be decreased for 3 months and were significantly lower in arm 1 only at Month 1 ($P<0.05$). Cytotoxic T cells (%) tended to be increased in arm 1 only at Month 1 ($P=0.076$).

Subjective symptoms such as anorexia and general malaise (especially anorexia) improved markedly but not significantly in arm 1. Statistical analysis could not be performed because of a small sample size.

8. Conclusions

Juzentaihoto is useful in gastric cancer patients undergoing postoperative adjuvant UFT.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Decreased white blood cell and granulocyte counts were observed in 1 patient in Arm 1 and 1 patient in Arm 2.

11. Abstractor's comments

The authors concluded that juzentaihoto used in combination with the anticancer agent (UFT) is useful in improving host-immunity and reducing adverse reactions to the anticancer agent. However, the only statistically significant difference was in the suppressor T cell % at Month 1 (significantly lower in the juzentaihoto combination group than in the control group). Otherwise, there was no significant difference between the two groups in suppressor T cell % at any other time points or in cytotoxic T cell % throughout the follow-up period, indicating that their conclusion was unjustified. Throughout the follow-up, white blood cell count and lymphocyte % tended to be higher in the combination group, indicating that the absolute lymphocyte count may have been significantly higher in the combination group. In addition, anorexia improved more in the combination group suggesting greater improvement in its nutritional status (but no significance could be demonstrated because of a small sample size). Difference in body weight gain % may have been significant although changes in body weight were not assessed. The data in this article needs re-analysis and re-interpretation.

12. Abstractor and date

Hoshino E, February 15 2009, 6 January 2010, 1 June 2010, 31 December 2013.