

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

Aoe H, Sumida Y, Kawahara N, et al. Efficacy of an erythropoietin preparation and Kampo medicines in preoperative autologous blood donation in cancer patients*. *Jikoketsu Yuketsu (Journal of Japanese Society of Autologous Blood Transfusion)* 1999; 12: 100-4 (in Japanese). [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the efficacy of juzentaihoto (十全大補湯) and ninjin'yoeito (人参養榮湯) combined with an erythropoietin (EPO) preparation in preoperative autologous blood donation in cancer patients.

2. Design

Randomized controlled trial (RCT).

3. Setting

Single hospital (Department of Obstetrics and Gynecology, Japanese Red Cross Society Himeji Hospital), Japan.

4. Participants

Ninety patients with gynecologic malignant tumors who visited the above institution between January 1992 and the end of November 1997 and preoperatively donated 800 mL or more of autologous blood.

5. Intervention

Intravenous administration of an iron preparation to patients with hemoglobin concentration of ≥ 14 g/dL. Randomization of patients with hemoglobin concentration of < 14 g/dL to receive intravenous iron preparation + Kampo formulation + EPO or intravenous iron preparation + EPO.

Arm 1: intravenous administration of an iron preparation (240 mg weekly) from the day of the first donation through the day before the operation.

Arm 2: intravenous administration of an iron preparation (240 mg weekly) + intravenous drip infusion of 6000 units of EPO three times weekly, from the day of the first donation through the day before the operation.

Arm 3: intravenous administration of an iron preparation (240 mg weekly) + intravenous drip infusion of 6000 units of EPO three times weekly + oral administration of TSUMURA Juzentaihoto (十全大補湯) Extract Granules or Ninjin'yoeito (人参養榮湯) Extract Granules 2.5 g t.i.d (before meals), from the day of the first donation through the day before the operation.

6. Main outcome measures

Hematological profile: RBC count, hemoglobin, hematocrit, reticulocyte count, etc., measured before donation (before administration) and preoperatively (immediately after completion of administration).

Serum biochemical profile: total protein, albumin, and iron concentrations, determined before donation (before administration) and preoperatively (immediately after completion of administration).

Hemoglobin increment: pre-donation hemoglobin concentration \times volume of donated blood/volume of circulating blood – (pre-donation hemoglobin concentration – preoperative hemoglobin volume).

7. Main results

The increase in reticulocyte count from the time of donation to the time of operation was larger in the Kampo group (n=36) and EPO group than in the iron group (n=15). The increase in hemoglobin level was larger in the EPO group (1.73 ± 1.30 g/dL) than the iron group (0.92 ± 0.70 g/dL), and significantly ($P < 0.05$) larger in the Kampo group (2.33 ± 1.11 g/dL) than the EPO group.

8. Conclusions

Combining a Kampo formulation with an iron preparation plus EPO enhances the clinical effectiveness of preoperatively donated autologous blood.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

The finding that adding juzentaihoto or ninjin'yoeito to the preoperative donation management protocol enhances the increase in blood hemoglobin concentration suggests that the hematological profile of donated autologous blood is better after use of the combination than after use of only the iron preparation plus EPO. Thus, this finding is clinically significant. With the accumulation of more cases, a safety study is expected including an examination of the possibility that complementary medicines promote cancer cell growth.

12. Abstractor and date

Ushiroyama T, 1 April 2008, 31 December 2013.