

### 3. Blood Diseases including Anaemia

#### Reference

Nakamaoto H, Mimura T, Honda N. Orally administrated Juzen-taiho-to/TJ-48 ameliorates erythropoietin (rHuEPO)-resistant anemia in patients on hemodialysis. *Hemodialysis International* 2008; 12: S9-14. CENTRAL ID: CN-00667345, Pubmed ID: 18837771

#### 1. Objectives

To evaluate the efficacy and safety of juzentaihoto (十全大補湯) for erythropoietin-resistant anemia in patients on hemodialysis.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

One university hospital and 1 general hospital, Japan.

#### 4. Participants

Forty-two patients on hemodialysis with erythropoietin-resistant anemia.

#### 5. Intervention

Arm 1: TSUMURA Juzentaihoto (十全大補湯) Extract Granules 2.5 g t.i.d. for 12 weeks (n=22).

Arm 2: not treated with TSUMURA Juzentaihoto (十全大補湯) Extract Granules (n=20).

Patients in the two groups were on the same dietary regimen and dialysis program.

#### 6. Main outcome measures

Hemoglobin level.

#### 7. Main results

While Hb level increased nonsignificantly from  $8.3\pm 0.7$  to  $8.5\pm 0.5$  g/dL in arm 2, it increased significantly from  $8.4\pm 1.1$  to  $9.5\pm 1.3$  g/dL in arm 1 ( $P=0.0272$ ).

#### 8. Conclusions

Treatment with TSUMURA Juzentaihoto Extract Granules is effective for erythropoietin-resistant anemia in patients on hemodialysis.

#### 9. From Kampo medicine perspective

None.

#### 10. Safety assessment in the article

No adverse event (complication, abnormality in blood chemistry) was reported in the juzentaihoto group.

#### 11. Abstractor's comments

This RCT was conducted in many patients with erythropoietin-resistant anemia and using a double-blind design. However, it is questionable that this trial was not placebo-controlled and no statistical analysis was mentioned. Given the decrease in serum C-reactive protein (CRP) level and negative correlation between serum CRP and Hb levels in the juzentaihoto group (and the absence of a decrease in serum CRP level and negative correlation in the non-treatment group), the authors assume that juzentaihoto may act, at least in part, as an anti-inflammatory agent. This is an interesting assumption that may suggest a basic research question.

#### 12. Abstractor and date

Kogure T, 1 June 2010, 31 December 2013.