

**3. Blood Diseases including Anaemia****Reference**

Motoo Y, Mouri H, Ohtsubo K, et al. Herbal medicine ninjinyoeito ameliorates ribavirin-induced anemia in chronic hepatitis C: a randomized controlled trial. *World Journal of Gastroenterology* 2005; 11: 4013-7. CENTRAL ID: CN-00522971, Pubmed ID: 15996025

**1. Objectives**

To evaluate the efficacy and safety of ninjin'yoeito (人参養榮湯) for ribavirin-induced anemia.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One university hospital, Japan.

**4. Participants**

Twenty-three chronic hepatitis C patients treated with interferon alpha-2b and ribavirin. Five of them withdrew from the study.

**5. Intervention**

Arm 1: designated "the NY group" and treated with IFN $\alpha$ -2b and ribavirin plus TSUMURA Ninjin'yoeito (人参養榮湯) Extract Granules (9 g, orally), n=10.

Arm 2: designated "the control group" and treated with interferon alpha-2b (IFN $\alpha$ -2b) and ribavirin, n=13

IFN $\alpha$ -2b was administered for a total of 24 weeks at a dose of 10 MU intramuscularly, 6 days per week for the first 2 weeks and 3 days per week for the following 22 weeks. Ribavirin was orally administered for 24 weeks at a dose of 800 mg/day (if the patient's body weight was  $\geq$  60 kg) or 600 mg/day (body weight < 60 kg).

**6. Main outcome measures**

Maximum increase in red blood cell count (max $\Delta$ RBC), maximum increase in hemoglobin level (max $\Delta$ Hb) minimum hemoglobin level (min Hb), white blood cell count (WBC), platelet count (Plt), T-helper 1 cell (Th1) count, T-helper 2 cell (Th2) count, Th1/Th2, and glutathione peroxidase level in peripheral blood.

**7. Main results**

Peripheral max $\Delta$ Hb and min Hb were significantly improved in the NY group ( $P=0.026$  and  $P=0.079$ , respectively). No between-group differences were observed in max $\Delta$ RBC, WBC count, Plt count, Th1 count, Th2 count, Th1/Th2, and glutathione peroxidase level. Antiviral effects were not different, either.

**8. Conclusions**

Ninjin'yoeito is an effective and safe treatment for ribavirin-induced anemia.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Adverse reactions specific to ninjin'yoeito were not observed.

**11. Abstractor's comments**

This study showed the efficacy of ninjin'yoeito for ribavirin-induced anemia. The authors speculated that the mechanism of action of this drug is the activation of undifferentiated erythroid cells and antioxidation.

**12. Abstractor and date**

Kogure T, 15 June 2007, 1 April 2008, 31 December 2013.