#### **Evidence Reports of Kampo Treatment**

Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

# 3. Blood Diseases including Anaemia

#### Reference

Yanagihori A, Miyagi M, Hori M, et al. Efficacy of ninjin'yoeito for iron deficiency anemia\*. *Rinsho to Kenkyu (Japanese Journal of Clinical and Experimental Medicine*) 1995; 72: 2605-8 (in Japanese). Ichushi Web ID: 1996162428, MOL, MOL-Lib

# 1. Objectives

To evaluate the efficacy of ninjin'yoeito (人参栄養湯) for iron deficiency anemia due to menorrhagia.

#### 2. Design

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

### 3. Setting

Department of Obstetrics and Gynecology, Toho University Sakura Medical Center, Japan.

### 4. Participants

Thirty-nine patients diagnosed with iron deficiency anemia (hemoglobin, 9.0 mg/dL or less) due to menorrhagia and metrorrhagia associated with uterine myoma, uterine adenomyoma, endometrial polyp, etc.

# 5. Intervention

Arm 1: Kanebo (currently Kracie) Ninjin'yoeito (人参栄養湯) Extract Granules 5 g/day + ferrous citrate (Ferromia) 100 mg/day for 4 weeks (n=21).

Arm 2: ferrous citrate (Ferromia) 100 mg/day for 4 weeks (n=18).

### 6. Main outcome measures

Changes in hematological values, including serum iron and ferritin and subjective symptoms (general malaise, shortness of breath, and palpitation) from pre- to post-dose.

#### 7. Main results

Elevation in hemoglobin value from pre- to post-dose was significantly higher in arm 1 (P<0.01). Palpitation and shortness of breath and symptoms for which ninjin'yoeito should be effective (anorexia, night sweats, and cold limbs) were similarly improved in both arms.

### 8. Conclusions

Ninjin'yoeito combined with an iron preparation is effective for iron deficiency anemia due to menorrhagia.

# 9. From Kampo medicine perspective

The effects of the components of ninjin'yoeito (ninjin [人参], byakujutu [白朮], and onji [遠志]) on bone marrow are suggested.

# 10. Safety assessment in the article

None.

# 11. Abstractor's comments

This study investigated the hematopoietic effect of ninjin'yoeito on anemia due to menorrhagia. Given accumulated clinical reports supporting the efficacy of ninjin'yoeito for myelosuppression associated with anticancer drug treatment, its effect on iron deficiency anemia was expected. Lack of improvement in the symptoms for which ninjin'yoeito should be effective other than anemia, such as night sweats and cold limbs, may warrant review of the Kampo criteria for application of ninjin'yoeito, as pointed out by the authors in the text. Future reports are awaited.

# 12. Abstractor and date

Nakata H, 1 January 2009, 6 January 2010, 1 June 2010, 31 December 2013.