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

## 15. Ante/Post-partum Diseases

#### Reference

Ushiroyama T, Sakuma K, Souen H, et al. Xiong-gui-tiao-xue-yin (kyuki-chouketsu-in), a traditional herbal medicine, stimulates lactation with increase in secretion of prolactin but not oxytocin in the postpartum period. *The American Journal of Chinese Medicine* 2007; 35: 195-202. CENTRAL ID: CN-00609546, Pubmed ID: 17436360

## 1. Objectives

To evaluate the postpartum lactation-promoting effect and safety of kyukichoketsuin (キュウ帰調血飲).

#### 2. Design

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

#### 3. Setting

Osaka Medical College Hospital, Japan.

#### 4. Participants

Eighty-two women who had normal spontaneous delivery.

## 5. Intervention

Arm 1: TAIKODO Kyukichoketsuin (キュウ帰調血飲) Extract Granules (Kanebo) 2.0 g t.i.d. for 6 days, n=41.

Arm 2: methylergometerine maleate 0.375 mg/day in 3 divided doses for 6 days, n=41.

#### 6. Main outcome measures

Amount of lactation, blood prolactin concentration.

#### 7. Main results

The amount of lactation was significantly increased in arm 1 on day 4 to  $276.5\pm21.4$  g (compared with  $155.3\pm61.2$  g in arm 2; *P*<0.042), on day 5 to  $342.6\pm43.6$  g (compared with  $245.5\pm59.4$  g in arm 2; *P*<0.038), and on day 6 to  $413.7\pm68.1$  g (compared with  $293.3\pm98.5$  g in arm 2; *P*<0.046). In addition, blood prolactin concentration was significantly elevated in arm 1 (compared with arm 2) on day 1 (*P*<0.037) and 6 (*P*<0.0024) after delivery.

## 8. Conclusions

Kyukichoketsuin may increase postpartum lactation.

**9.** From Kampo medicine perspective Mentioned in discussion.

# **10.** Safety assessment in the article No adverse drug reactions occurred.

## **11.** Abstractor's comments

While in Japan the RCT-envelope method of allocation often fails to maintain randomization, this study can suggest that kyukichoketsuin increases postpartum lactation. Kyukichoketsuin, also known as kyukihoketsuto, is considered to be effective for various postpartum symptoms including *qiketsukyoson* (気血虚損, qi and blood deficiencies), *hiikyojaku* (脾胃虚弱, hypofunctioning of spleen and stomach), *orofugyo* (悪露不行, lochiometra), *kyoketsukata* (去血過多, hypermenorrhea), *inshokusissetsu* (飲食失節, crapula), and *dokisosho* (怒気相衝, anger) (In: *Wanbinghuichun* [萬病回春], *Recovery from All Ailments*).

## **12.** Abstractor and date

Okabe T, 27 November 2008, 1 June 2010, 31 December 2013.