

## 13. Diseases of the Musculo Skeletal System and Connective Tissue

### Reference

Seo BK, Ryu SR, Kang JW, et al. Clinical study of the efficacy and safety of Jetongdan on patients with osteoarthritis of the knee. *Daehan-Hanui-Hakhoeji (Journal of Korean Oriental Medical Society)* 2005; 26(2): 231–40 (in Korean with English abstract).

### 1. Objectives

To evaluate the effect of Jetongdan on Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) OA (an index of knee osteoarthritis severity).

### 2. Design

Double-blinded randomized controlled trial (DB-RCT).

### 3. Setting

One Oriental hospital (Kyunghee University Medical Center), Republic of Korea.

### 4. Participants

Knee osteoarthritis patients (n=80).

### 5. Intervention

Arm 1: Jetongdan treatment for 8 weeks, 3 doses per day, 3 capsules per dose (n=42).

Arm 2: Placebo treatment. Placebo capsule with same treatment regimen (n=38).

If non-steroidal inflammatory drugs were used, treatment was started after a 1-week washout period.

### 6. Main outcome measures

WOMAC; erythrocyte sedimentation rate (ESR).

Each index was recorded before treatment, and 4 weeks and 8 weeks after treatment.

### 7. Main results

Treatment significantly accelerated the decrease in composite WOMAC score and WOMAC physical function subscore in Arm 1 compared with Arm 2 ( $P<0.001$ ), and the between-group differences were significant ( $P<0.05$ ). Both treatments also significantly accelerated the decrease in WOMAC pain subscore ( $P<0.001$ ) but had no effect on ESR.

### 8. Conclusions

Jetongdan treatment improves WOMAC score and ESR score. Failure to demonstrate improvement in pain and stiffness is attributed to between-group differences in baseline characteristics. Further study using a larger sample is recommended.

### 9. Safety assessment in the article

Jetongdan treatment had no adverse effect on kidney and liver function:

### 10. Abstractor's comments

This randomized, double-blind study evaluates the efficacy and safety of Jetongdan in patients with osteoarthritis. However, there was a significant between-group difference in pretreatment WOMAC scores ( $48.3\pm 12.8$  [Arm 1] vs.  $56.3\pm 16.7$  [Arm 2],  $P=0.038$ ) indicating bias due to inadequate randomization. The contents and formulation were not described, and the reasons for the change in number of subjects included for analysis was not provided. P-values but not the WOMAC scores and changes in ESR were presented. Jetongdan treatment was not individualized, so the result of this study is difficult to apply realistically in clinical settings.

### 11. Abstractor and date

Kim JI, 28 June 2010.