

## 5. Psychiatric/Behavioral Disorders

### Reference

Arai YC, Kawanishi J, Sakakima Y, et al. The effect of the kampo medicine yokukansan on preoperative anxiety and sedation levels. *Evidence-Based Complementary and Alternative Medicine* 2014: 1-4. doi: 10.1155/2014/965045 Pubmed ID: 24799947

#### 1. Objectives

To evaluate the effectiveness and safety of yokukansan (抑肝散) in preoperative sedation.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Single facility (hospital surgery department).

#### 4. Participants

Seventy patients whose physical status was rated I or II (American Society of Anesthesiologists) before hemicolectomy (ages: 30-85; 23 females and 47 males).

#### 5. Intervention

Arm 1: TSUMURA Yokukansan (抑肝散) extract granules (2.5 g) taken orally 1.5 hours before general anesthetic (n=36).

Arm 2: Diazepam (5 mg) taken orally 1.5 hours before general anesthetic (n=34).

#### 6. Main outcome measures

Intensity of anxiety immediately prior to anesthesia, using a verbal rating scale (VRS); Level of sedation using the modified Observer's Assessment of Alertness/Sedation Scale (OAA/S).

#### 7. Main results

There was no significant difference between arms 1 and 2 in the intensity of anxiety on the VRS. The levels of sedation on the OAA/S showed statistically significant sedation in arm 2 compared to arm 1 ( $P<0.05$ ).

#### 8. Conclusions

Compared to diazepam, yokukansan does not excessively sedate patients.

#### 9. From Kampo medicine perspective

None.

#### 10. Safety assessment in the article

There were no adverse drug reactions in either the yokukansan group or the diazepam group.

#### 11. Abstractor's comments

This clinical trial evaluated the significance of using yokukansan in sedation prior to hemicolectomy. The authors concluded that sedation with yokukansan prior to surgery under general anesthesia is not excessive. However, because the trial was not designed as a non-inferiority study, it does not clarify whether diazepam and yokukansan have the same level of effectiveness in suppressing anxiety. Hopefully the authors will conduct a trial that indicates non-inferiority by comparing yokukansan administration with diazepam administration for the suppression of anxiety prior to surgery under general anesthesia, and indicates the effectiveness of yokukansan administration for the suppression of anxiety prior to surgery under general anesthesia in comparison with the use of placebo or no preoperative drugs prior to surgery, as the next stage of their research.

#### 12. Abstractor and date

Koike H, 31 March 2017.