

5. Psychiatric/Behavioral Disorders**Reference**

Nishimatsu H, Kitamura T, Yamada D, et al. Improvement of symptoms of aging in males by a preparation LEOPIN ROYAL containing aged garlic extract and other five of natural medicines-comparison with traditional herbal medicines (Kampo). *Aging male* 2014; 17: 112-6. CENTRAL ID: CN-00992899, Pubmed ID: 24844765

1. Objectives

To compare the efficacy of LEOPIN ROYAL with that of Kampo medicines for aging in males.

2. Design

Randomized controlled trial (RCT).

3. Setting

One department of urology in a university hospital and one department of urology in a hospital, Japan.

4. Participants

Forty-nine males who complained of aging symptoms and underwent physical examinations at the Department of Urology, Faculty of Medicine, University of Tokyo.

5. Intervention

Arm 1: LEOPIN ROYAL for 6 months (n=24).

Arm 2: Kamishoyosan (加味逍遙散) (n=20), hangekobokuto (半夏厚朴湯) (n=1), saikokaryukotsuboreito (柴胡加竜骨牡蛎湯) (n=1), hochuekkito (補中益氣湯) (n=1), goshajinkigan (牛車腎氣丸) (n=1), and hachimijiogan (八味地黄丸) for 6 months (n=1) (manufacturers unknown).

6. Main outcome measures

Aging Males' Symptoms (AMS) scale; International Index of Erectile Function with 5 questions (IIEF-5); Androgen Deficiency in the Aging Male (ADAM) score; Self-Rating Questionnaire for Depression (SRQ-D) score; and serum levels of the following hormones: total testosterone, free testosterone, follicle-stimulating hormone (FSH), luteinizing hormone (LH), prolactin (PRL), and estradiol (E2).

7. Main results

In the LEOPIN ROYAL arm compared to the Kampo arm, somatic and psychological subscores and the total score in the AMS scale were significantly lower ($P<0.01$ for somatic sub-score; $P<0.01$ for psychological subscore; $P<0.01$ for total score), and the AMS somatic score and IIEF-5 score were significantly improved ($P<0.01$ for somatic subscore; $P=0.019$ for IIEF-5 score). Blood levels of total testosterone, free testosterone, FSH, LH, PRL, or E2 remained unchanged in the two arms.

8. Conclusions

LEOPIN ROYAL is more effective than kamishoyosan for symptoms of aging in males.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No special problems were noted.

11. Abstractor's comments

In this study, kamishoyosan was the control for LEOPIN ROYAL, but hangekobokuto, saikokaryukotsuboreito, hochuekkito, goshajinkigan, and hachimijiogan were also used as controls in one subject each, depending on their symptoms. For symptoms such as decreased libido, hachimijiogan was presumably more effective than LEOPIN ROYAL; therefore, presenting in this article information about each Kampo formulation, rather than information about the group of Kampo formulations, would have been more valuable.

12. Abstractor and date

Nakata H, 31 March 2017.