Altern Integr Med 2018, Volume 7
DOI: 10.4172/2327-5162-C6-057

The effect of herbal mixture on male climacteric syndrome: Double-blind, randomized, placebo-controlled, parallel study

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We investigate the effects of herbal formulation Ojayeonjonghwan (KH-204) in men with late-onset hypogonadism(LOH) symptoms. All subjects had a 4-week wash-out period before the start of the study. Before and after the study, physical examination, vital sign measurements, PSA, the male hormone, lipid profile, and serological tests, questionnaires about LOH-related symptoms such as AMS, ADAM, IIEF, IPSS were performed. The treatment was performed for a total of 8 weeks. After 8 weeks, questionnaires and serological tests were performed to confirm the effectiveness and safety of the drug. The changes of each variable in each group were compared, and the difference between the two groups was compared and analyzed. A Total of 78 men were enrolled and randomly assigned to the control group (n=39) or KH-204 group (n=39). None of both groups were dropped out. Mean ages of patients, vital sign, BMI did not differ between the two groups. AMS total score of control and KH-204 group were both improved at 4 weeks (p=0.027, 0.003) and 8 weeks (p= 0.010 vs <0.001). AMS total score was decreased at 8 weeks compared to baseline (5.67 points in the KH-204 group vs 2.28 points in the control group), and there was a statistically significant difference between the two groups (p-value = 0.0061). The number of androgen deficiency male, which was classified according to the ADAM questionnaire, in the control group was changed to 36 at 8 weeks. On the other hand, in the KH-204 group, it decreased to 24 at 8 weeks, showing a statistically significant difference from the control group (p=0.013). At 8 weeks, the total IIEF score of control (+3.82, p=0.025) and KH-204 (+6.21, p=0.001) group were both improved, and there was no statistically significant difference in the degree of improvement between the two groups (p=0.303). There was no statistically significant difference of laboratory findings including testosterone, free testosterone, PSA, lipid profiles, in intra-group changes and inter-group comparisons. Mild adverse events were noted in three participants of KH-204 group (loose stool, common cold, dry eye), but they were recovered without treatment. KH-204 was found to be effective in all LOH-related symptoms without changing laboratory results. KH-204 may be safely used for the treatment of aging male with LOH-related symptoms.

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