Original Article
CLINICAL TRIALS: BEHAVIOR, PHARMACOTHERAPY, DEVICES, SURGERY

Obesity

Antiobesity Effect of *Gynostemma pentaphyllum* Extract (Actiponin): A Randomized, Double-Blind, Placebo-Controlled Trial

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Objective: The effects of actiponin was investigated, a heat-processed *Gynostemma pentaphyllum* extract, on body weight, fat loss, and metabolic markers of Korean participants in a 12-week, randomized, double-blind, placebo-controlled clinical trial.

Design and Methods: Obese participants (BMI $\geq$ 25 kg m^{-2} and WHR $\geq$ 0.90 for male or WHR $\geq$ 0.85 for female) who had not been diagnosed with any disease and met the inclusion criteria were recruited for this study. The 80 subjects were randomly divided into actiponin ($n = 40$, 450 mg day^{-1}) and placebo ($n = 40$) groups. Outcomes included measurement of efficacy (abdominal fat distribution, anthropometric parameters, and blood lipid profiles) and safety (adverse events, laboratory test results, electrocardiogram data, and vital signs).

Results: During 12-week of actiponin supplementation, total abdominal fat area, body weight, body fat mass, percent body fat, and BMI were significantly decreased ($P = 0.044$, $P < 0.05$, $P < 0.0001$, $P < 0.0001$, and $P < 0.05$, respectively) in the actiponin group compared to the placebo group. No clinically significant changes in any safety parameter were observed.

Conclusion: Our study revealed that actiponin is a potent antiobesity reagent that does not produce any significant adverse effects. These results suggest that actiponin supplementation may be effective for treating obese individuals.

Obesity (2014) **22**, 63–71. doi:10.1002/oby.20539

Introduction

According to the World Health Organization, overweight and obesity are defined as abnormal or excessive fat accumulation that increases the risk of type 2 diabetes, cardiovascular disease, and several types of cancers (1,2). A number of promising antiobesity drugs are developed each year with demonstrable efficacy in cell lines and animal models. However, only a few of these reagents enter and stay in the market because most are associated with serious side effects.

Only a few antiobesity drugs have been approved by the United States Food and Drug Administration for long-term use. One of these is orlistat (Xenical) that reduces intestinal fat absorption by inhibiting pancreatic lipase (3). Another, sibutramine (Meridia), decreases appetite by inhibiting the deactivation of the neurotransmitters in the brain but was withdrawn from the United States and Canadian markets in October 2010 because of increased risk of cardiovascular disease (4,5). Because of potential adverse side effects, it is recommended that anti-obesity drugs only be prescribed for

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Funding agencies: This work was supported by a grant (PF06212-00) from the Plant Diversity Research Center of the 21st Century Frontier Research Program funded by the Ministry of Education, Science and Technology, and by a grant (A111345) from the Korean Health Technology R&D Project from the Ministry of Health and Welfare, Republic of Korea.

Disclosure: None of the authors have any potential conflicts of interest related to the contents of this article.

Author Contributions: The authors' responsibilities were as follows: YSC and SWC conceived the study concept and designed the experiments. SHP, SYK, and MRO conducted the experiments. SHP, PBTP, TLH, SWC, and YSC analyzed and interpreted the data, and wrote the manuscript. SWC and YSC had primary responsibility for the final content. All authors read and approved the final version of the manuscript.

Soo-Hyun Park and Tae-Lin Huh contributed equally to this work.

Additional Supporting Information may be found in the online version of this article.

Received: 30 November 2012; **Accepted:** 27 May 2013; **Published online 26 June 2013. doi:10.1002/oby.20539**