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A randomized double-blind placebo-controlled clinical trial of a product containing pumpkin seed extract and soy germ extract to improve overactive bladder-related voiding dysfunction and quality of life

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ABSTRACT

Overactive bladder (OAB) has become an increasing field of interest. Traditional use indicates that pumpkin seed (*Cucurbita pepo* L.) may be helpful in combating its symptoms. Additionally, soy isoflavones (*Glycine max*) are well-documented for hormonal imbalance related indications. The present randomized, double-blind, placebo-controlled study evaluated efficacy and safety of Cucuflavone (containing extracts of pumpkin seed and soy germ) in 120 subjects suffering from OAB. After 12 weeks, subjects taking Cucuflavone experienced a significant reduction versus baseline, in (1) urination frequency, (2) urgency, (3) incontinence frequency, maximum urgency score, (5) nocturnal urination frequency and (6) OAB-symptom scale. The placebo group reached significant differences for (1), (3) and (6). No adverse events or abnormal changes in safety parameters occurred. Thus, the combination of pumpkin seed and soy germ extract can be used as natural alternative to relieve symptoms of OAB and to improve quality of life.

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1. Introduction

According to the definition of the International Continence Society (ICS), overactive bladder symptom (OAB) is defined as

the involuntary contraction of the detrusor when the bladder is full, regardless of the will of inhibition. It usually refers to frequent urination or nocturia, and it may or may not accompany urge incontinence (Abrams et al., 2002). While the root cause of overactive bladder symptom is unknown, with some

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exceptions, it happens more frequently among the elderly. Worldwide around 50 to 100 million people are assumed to suffer from this symptom, and the actual numbers might be even much higher as it is still seen as a taboo topic.

Improvements can be made for OAB symptom by investigating and treating the correctable causes. Anticholinergic medication and behavior modification are first choices of treatment if no cause can be found. It is known that 50–80% of the OAB symptoms are improved if these two treatment methods are applied by stages or in parallel. However, pharmacologic interventions are often accompanied by side effects and are not suitable for everyone. With recent progress in medical and nutrition sciences, natural products and health promoting foods have received much attention from both the public and health professionals. Thus, nutraceuticals and functional foods containing clinically proven natural ingredients that support bladder control are a gentle alternative for people suffering from OAB. Being easily available in health food stores, such products also help in bringing relief to the huge number of patients who are reluctant to seek professional help and are suffering from OAB in silence. So far there are few natural remedies known to influence the symptoms of OAB, such as horsetail, saw palmetto, and pumpkin seed, which is part of the study product within this clinical trial.

Seeds from the medicinal pumpkin, *Cucurbita pepo*, are officially monographed for the use with irritable bladder symptoms and micturition problems of benign prostatic hyperplasia (BPH) stages 1 and 2 (Blumenthal, Goldberg, & Brinckmann, 2000; ESCOP, 2009). Although pumpkin seeds became known worldwide owing to traditional use, recent scientific evidence for its effects is scarce. The use of soy isoflavones however is well documented for several indications related to hormonal imbalances (Chen, Ho, Lam, Ho, & Woo, 2003; Ye et al., 2012).

Studies performed in the past showed that a premixed blend of pumpkin seed extract and soy germ extract was able to improve urinary incontinence as well as BPH related symptoms in different populations (Sogabe & Terado, 2001; Terado, Sogabe, & Saito, 2004; Yanagisawa & Satoh, 2003). However, the limitation of these studies was the fact that they were not placebo-controlled. Thus, this study is intended to examine the efficacy of the combination product of the two extracts described above called Cucuflavone on urination frequency, urinary loss and several other parameters connected to urinary incontinence in a placebo-controlled setting. Additionally, the safety of treatment with the extract combination was assessed.

2. Materials and methods

2.1. Study design

The study was a randomized, double-blind, placebo-controlled, 12-week, prospective, parallel group trial conducted at the Ehwa Woman's University in Korea. The protocol ECT 221-3-37 was approved on March 17, 2010 by the institutional review board of the hospital and complies with KGCP, ICH-GCP and law and regulation related to life ethics and safety.

2.2. Study participants

One hundred and twenty women between the ages of 35 and 70 years, suffering from urinary urgency, frequent urination and nocturia, with or without urge incontinence, for over 3 months, were recruited through newspaper advertisements, health columns in public media and ad posters. Complete inclusion and exclusion criteria can be found in Table 1. All eligible subjects who were in good health according to their medical history, physical examination, and routine laboratory tests, and who signed written informed consent were enrolled.

2.3. Interventions

2.3.1. Study products

Study products were 500 mg dark orange coated tablets containing 250 mg of a premixed blend (Cucuflavone), or 250 mg maltodextrin (placebo), and excipients per tablet. The premixed blend contained 87.5% pumpkin seed extract (EFLA®940) and 12.5% soy germ extract (Soylife®40) and was obtained from Frutarom Switzerland Ltd, Wädenswil, Switzerland. The pumpkin seed extract was manufactured from defatted pumpkin seed of *C. pepo* L. by extraction with 60% (w/w) ethanol followed by a patented filtration procedure (EFLA®Hyperpure), mixing with additives and drying. The drug to extract ratio (DER) was 15–25:1 (w/w). The extract obtained in this manner has been shown to be optimal for functional food and dietary supplement applications by providing increased stability and solubility as well as proven efficacy. The soy germ extract was manufactured by using cracked roasted soybean germs which were extracted through aqueous ethanol extraction, spray-dried and standardized.

Characteristic components of the premixed blend are an isoflavone content (daidzin, genistin, glycitin) of 32–48 mg/g and

Table 1 – Inclusion and exclusion criteria for enrolment.

Inclusion criterion	Exclusion criterion
Symptoms > 3 months of:	Serious liver, kidney or heart disease
Urination frequency > 8×/day	Sensitivity to pumpkin seed or soybean
Nocturia > 2×/night	Treatment for overactive or neurogenic bladder, acute or within <3 months
	History of surgery for stress urinary incontinence
	Urinary infections
	Diabetes, spine disorder or urinary obstruction
	Concurrent medication that could affect the symptoms of OAB
	History of drug or alcohol abuse
	Pregnant or breastfeeding women and women with the possibility of getting pregnant

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