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A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIAL: EVALUATING SAFETY AND EFFICACY OF A COMPOSITION OF PURIFIED AND SPECIFIC CYTOPLASM EXTRACTS OF POLLEN (PSCEP), PUMPKIN SEED EXTRACT AND VITAMIN E (FEMAXEEN®) IN WOMEN WITH STRESS URINARY INCONTINENCE.

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OBJECTIVE

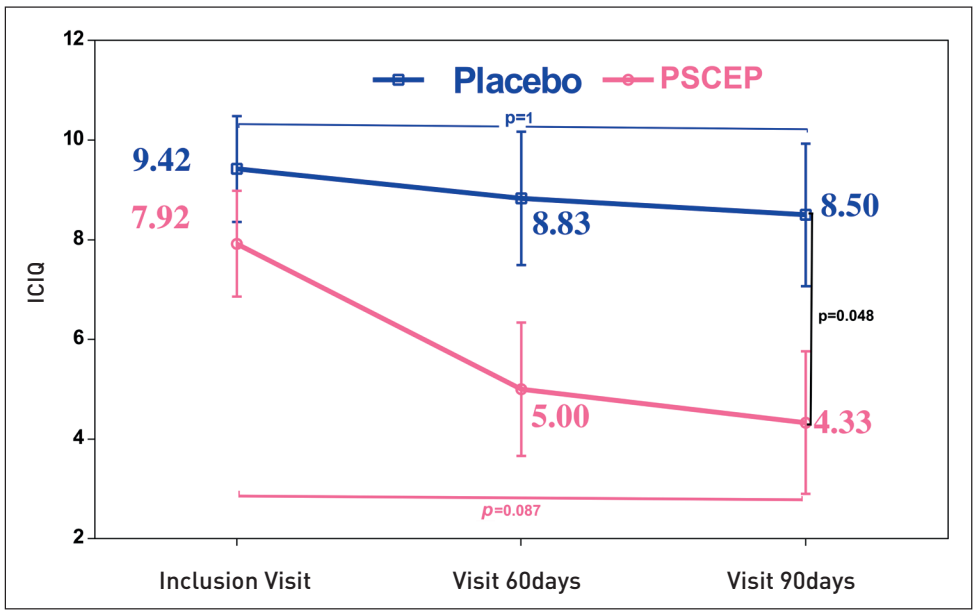
To assess the effect of a composition of PURIFIED AND SPECIFIC CYTOPLASM EXTRACTS OF POLLEN (PSCEP), PUMPKIN SEED EXTRACT AND VITAMIN E (FEMAXEEN®) for women with stress urinary incontinence.

METHODS

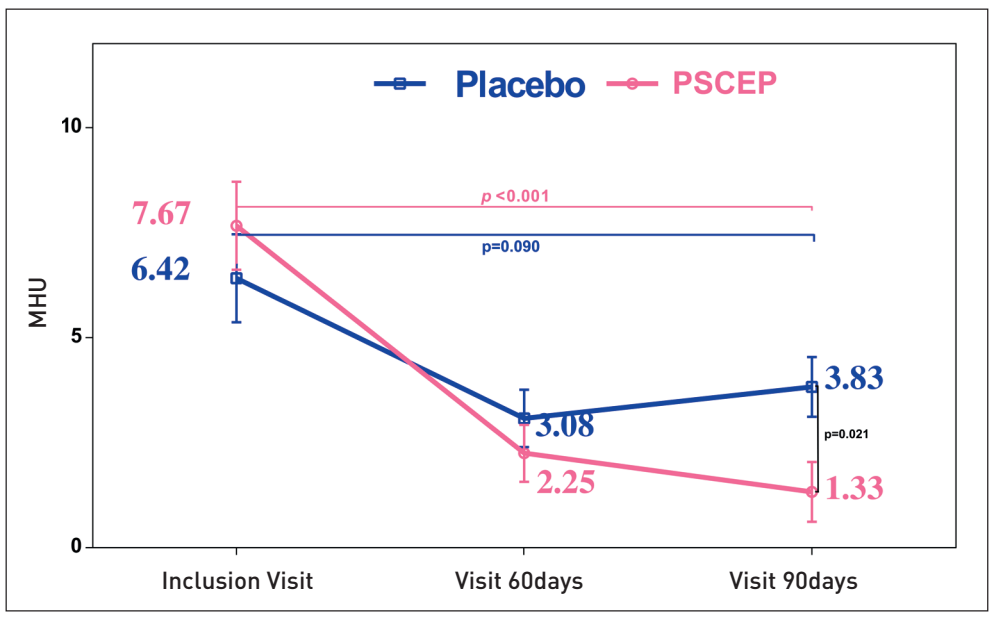
A randomized, double-blind, placebo-controlled clinical trial evaluated the effect of PSCEP (n=12) versus placebo (n=12). The efficacy was analyzed after three months treatment on both groups with the following questionnaires: The International Consultation on Incontinence-Urinary Incontinence Short Form (ICIQ-UI SF), the Measure of Urinary Handicap (MHU) Questionnaire and the Sandvik Incontinence Severity Index.

RESULTS

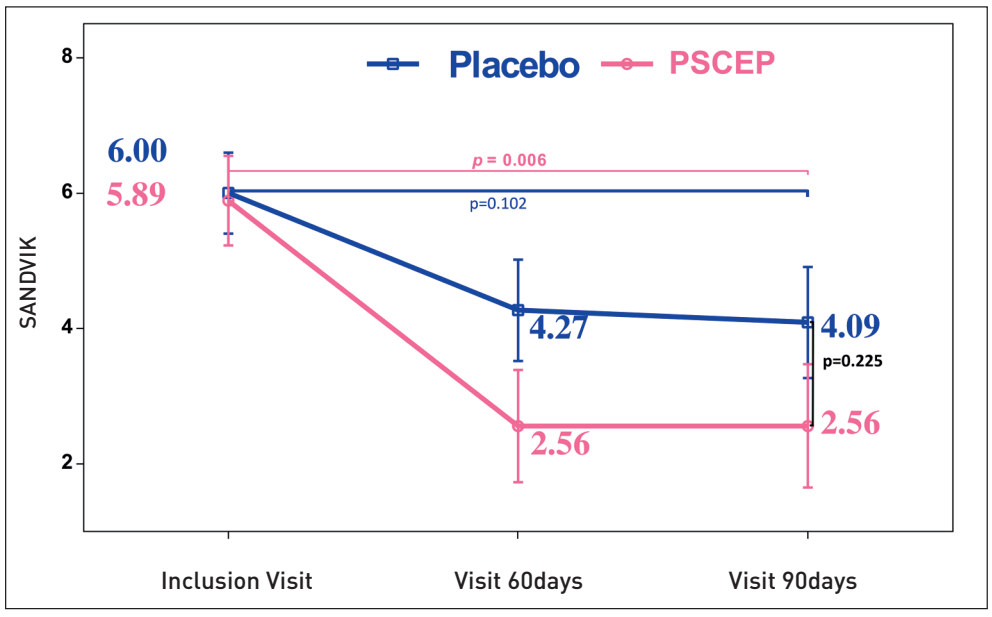
PSCEP was safe and well tolerated. In the ICIQ-UI SF a significant improvement in comparison with the placebo group was observed after 3 months (p=0.048). (Figure 1).



In the MHU a significant improvement in the PSCEP group was observed (p<0.001) compared to baseline and a significant improvement after 3 months of treatment compared to the placebo group (p = 0.021). (Figure 2).



Regarding the Sandvik Index, there was a significant improvement after 3 months of treatment in the PSCEP group compared to baseline (p =0,006). The placebo group did not show any significant changes at three months (p = 0.102). (Figure 3).
However, there was no difference with respect to the active group (p = 0.225), probably due to the small number of patients.



No side effects where observed in any of the groups.

CONCLUSION

This natural product (FEMAXEEN®) is a safe and effective treatment for women with stress urinary incontinence. Stress incontinence can result from weak muscles in the pelvic floor or a weak sphincter muscle at the neck of the bladder. Further studies are needed to confirm these results and to gain insights into the mechanism of action of this product on stress incontinence.

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