

TREATMENT OF URINARY INCONTINENCE: THE IMPORTANCE OF THE PLACEBO EFFECT**Aims of Study**

Urinary incontinence is very distressing and can have a serious impact on the quality of life of affected individuals. Existing pharmaceutical therapies provide marginal clinical benefit vs. placebo. This proof-of-concept study was conducted to evaluate the effectiveness of a novel peptide in the treatment of incontinence.

Methods

A double blind, placebo controlled clinical study was conducted to evaluate the effect of a single subcutaneous injection of a 30 day formulation of a peptide in the treatment of urinary incontinence in post-menopausal women (50-87 years). Although many subjects had symptoms of mixed incontinence, they were classified as primarily urge (N=5) or stress (N=30) and randomized to drug (peptide, N=18) or placebo (saline, N=17). Prior to and 4 weeks after treatment, subjects completed a 3day voiding diary and underwent a 24-hour pad test. Subjects also completed a questionnaire at the end of the study to provide their subjective assessment of the effect of treatment.

Results

At this sample size there were no significant differences between drug and placebo in this study. However, within the placebo treated group, improvements in voiding diary parameters and a positive subjective assessment of treatment effect were reported by a significant portion of the patients.

<u>Parameter</u>	% of placebo-treated subjects who improved or provided a positive subjective assessment
# micturitions/day	65
# incontinent episodes/day	41
# pads used/day	41
Volume of urine lost during 24-hour pad test	47
Subjective assessment of positive treatment effect	31
Would take drug again	56

Conclusions

The results of this study demonstrate and reinforce the significance of the placebo effect in studies evaluating the effects of pharmaceuticals on urinary incontinence. Previously reported studies, in which subjects received drug or placebo once or multiple times per day throughout the study, clearly demonstrate the placebo effect. Despite the fact that the subjects in this study were only treated once, a substantial portion of the placebo-treated subjects appears to have responded to saline. These data underline the importance of study design and stress the significance of the placebo effect in urinary incontinence studies.