A RANDOMIZED-PLACEBO CONTROLLED PILOT STUDY OF TAMSULOSIN, NAPROXEN, AND COMBINATION IN CATEGORY IIIA/IIIB CHRONIC PROSTATITIS/CHRONIC PELVIC PAIN SYNDROME

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INTRODUCTION AND OBJECTIVE: This pilot study tests the efficacy of standard treatments (alone and in combination) for chronic prostatitis using the NIH-CPSI as a treatment endpoint.
METHODS: 83 patients were recruited from a specialist CPPS clinic from January 2001 to June 2003, with duration of symptoms of at least 3 months. They were classified according to the 1995 NIH classification using Stamey localization and semen analysis. After a 4 week washout period, they were randomized in a double-blinded manner to placebo/placebo, tamsulosin (400mcg OD)/placebo, naproxen (500mg BD)/placebo and tamsulosin/naproxen. Assessments were made at 4 and 6 weeks. Primary endpoints were reduction in CPSI score (on a treatment completion basis) and number of responders as judged by a 25% and 50% improvement in score (on an intention to treat basis).
RESULTS: The mean total CPSI ranged from 22.7 to 26 in the 4 groups. 71% of patients completed treatments (equal in all groups). The median improvement in CPSI in the groups (4, 6 weeks) were as follows: placebo (2, 3), tamsulosin (2.5, 7), naproxen (3, 4.5) and combination (3, 3). The number of patients with a (25% and 50%) response to treatment at 6 weeks were as follows: placebo (4/20, 1/20), tamsulosin (6/20, 3/20) naproxen (7/22, 4/22) and combination (1/21, 0/21).
CONCLUSIONS: This pilot study suggests the efficacy of tamsulosin and naproxen as single agents for chronic prostatitis. Combination therapy was associated with a greater incidence of adverse events, and did not seem to benefit patients over placebo.

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