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## Abstract Reproduction Form B-1

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Title (type in CAPITAL LETTERS)	A RANDOMISED DOUBLE BLIND PLACEBO CONTROLLED CROSSOVER TRIAL OF THE EFFICACY OF L-ARGININE IN THE TREATMENT OF INTERSTITIAL CYSTITIS

**Aims of Study.** IC is a chronic condition of unknown aetiology, but recently the importance of Nitric Oxide (NO) in IC has been highlighted [1]. In previous open studies the precursor of NO synthesis, L-arginine, was shown to reduce the pain & frequency associated with IC [2]. We set up this double blind study to determine whether L-Arginine improved symptoms of IC over placebo.

**Methods.** Patients fulfilling the NIDDK [3] diagnostic criteria for IC were randomized to receive L-arginine (2.4 g/day) or placebo for one month. After a two-week "washout" they received the other medication. Patients were assessed at each stage by validated symptom index [4], voiding diary, MSU & record of adverse reactions. Results were compared using a t-test, a significance level of  $p < 0.05$  taken.

**Results.** We enrolled 16 patients, mean age 51.3 years, duration of IC 5.4 years, symptom index of 29.1, nocturnal frequency of 3.5 (vol. 182 ml) & daytime 12.7 (vol. 124 ml). Placebo caused no difference in any recorded variable over baseline. L-Arginine caused a statistically significant reduction in the overall symptom score of 2.2; this difference however was not reflected in voided volume, frequency or nocturia. Three patients felt better on L-arginine than placebo, eight did not report any improvement. Three patients withdrew due to side effects on L-arginine (severe headaches, night sweats & flushing). One patient was withdrawn due to poor compliance. We recorded UTI in one patient on placebo & L-Arginine.

**Conclusion.** L-Arginine leads to a statistically significant improvement in IC symptom index, but the magnitude of this effect is small. This observation may not be clinically significant since we recorded no improvement in other measured variables. We also noted severe side effects due to L-arginine & its use cannot be recommended in the treatment of IC.

#### References.

- [1] Urinary nitric oxide synthase activity and cyclic GMP levels are decreased with interstitial cystitis and increased with urinary tract infections. *J Urol*; 155(4): 1432-5. 1996.
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- [3] Summary of the National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases workshop in interstitial cystitis, National Institutes of Health, Bethesda, Maryland. *J Urol*; 140: 203-206, 1987.
- [4] The interstitial cystitis symptom index and problem index. *Urology*; 49(5A Suppl): 58-63, 1997.