

**CCF INSTITUTIONAL REVIEW BOARD  
PROJECT COMPLETION REPORT**  
Submit 1 copy to The Institutional Review Board, Wb2 (Ext. 42924)

IRB Number: 4562

Expiration Date: 08/14/2004

Principal Investigator: Ashok Agarwal, Ph.D

Department: Urology

Title: Lelvocarnitine Fumarate and Acetyl-L-Carnitine (ProXeed) combined Supplementation in Subfertile Males with High Reactive Oxygen Species

**[ X ] REQUEST TO TERMINATE**

**Final summary report**

The goal of this clinical trial was to evaluate, in a double-blind placebo controlled study, the effects of ProXeed supplementation for 6 months in patients with male factor infertility on their semen quality as well as on the levels of seminal reactive oxygen species.

Patients were enrolled after signing the IRB approved consent form. All patients received a thorough history and physical examination from our urologists as a part of the standard infertility work-up. Each patient was asked to donate a semen sample by masturbation after an abstinence of at least 48-72 hours. The collected samples were subjected to routine semen analysis (sperm count, motility, morphology by WHO and Kruger criteria), sperm motion kinetics by computerized semen analysis (CASA), and reactive oxygen species (ROS) measurement by chemiluminescence method and total antioxidant capacity using colorimetric assay. Repeat evaluations were performed after 15 days, 3 months and 6 months from the start of treatment.

During the initial period of the study till August 2003, we have enrolled only a total of 14 infertile male patients. Five patients have chosen to discontinue their participation in the study due to its length (6 months), which is further augmented by the possibility of being on placebo and not the actual treatment. For the same reasons, we have elected to discontinue further enrollment of patients. No new patients were enrolled in our study since August 2003.

**Adverse events:**

There were no adverse events reported during our clinical trial.