

Prevention of recurrent urinary infection: The role of immunotherapy with an E. Coli extract

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Recurrent urinary tract infections (UTIs) are a common clinical problem especially among women. Prophylactic treatment with antibiotics is limited, and alternatives such as immunotherapy are needed. UROVAXOM is a lyophilized extract of selected E. coli strains in a capsule formulation and has been shown to reduce the rate of UTIs in double-blind studies.

In a multicenter, double-blind study, adult female patients could be enrolled if they had acute UTI at the enrolment visit and positive bacteriological results in urinalysis ($\geq 10^3$ bacteria/ml). Patients received UROVAXOM or a matching placebo as follows: 1 capsule per day for 90 days, 3 months without treatment, then the first 10 days in Months 7, 8 and 9. Patients were followed-up for a total of 12 months. Primary efficacy criteria were UTI rates over 12 months, distribution of UTIs and proportion of patients with UTI.

A total of 453 patients were treated, 231 in the active group and 222 in the placebo group. The mean rate of post-baseline UTIs was significantly lower in the active group than in the placebo group (0.84 vs. 1.28; $p < 0.003$), corresponding to a 34% reduction of UTIs in patients treated with UROVAXOM. In the active group, 93 patients (40.3%) had 185 post-baseline UTIs, compared to 276 UTIs in 122 patients (55.0%) in the placebo group ($p = 0.001$). The safety profile of OM-89 was good and consistent with that reported in previous studies.

Immunotherapy with an E.coli extract significantly reduced the rate of UTI during the 12 months of the study including 3 months of treatment followed by three 10-day booster courses. These results further confirm that UROVAXOM is a valuable component of the management of recurrent UTI.