Introduction and Objectives: Recurrent urinary tract infections (UTI) are a common clinical problem especially among women. Prophylactic treatment with antibiotics is limited, and alternatives such as immunotherapy are needed. OM-89 is a lyophilized extract of selected *E. coli* strains in a capsule formulation and has been shown to reduce the rate of UTI in double-blind studies.

Material and Methods: In this multicenter, double-blind, randomized study, adult female patients could be enrolled if they had acute UTI at the enrolment visit and positive bacteriological results in urinalysis (≥10^4 bacteria/ml). Patients received OM-89 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 UTI and proportion of patients with UTI.

Results: A total of 453 patients were treated, 231 in the active group and 222 in the placebo group. The mean rate of post-baseline UTI was 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 OM-89. In the active group, 93 patients (40.3%) had 186 post-baseline UTI, compared to 276 UTI 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.

Conclusions: OM-89 significantly reduced the rate of UTI during the 12 months of the study including 3 months of treatment and three 10-day booster courses. These results further confirm that OM-89 is a valuable component of the management of recurrent UTI.

OBJECTIVE

To confirm the long-term preventive effect and safety over 12 months of an *E. coli* extract (OM-89) on recurrent UTI in a large cohort of female out-patients previously demonstrated in several 6-month double-blind studies.

MATERIALS AND METHODS

Study design

Double-blind, randomized, placebo-controlled trial in 52 European centers.

Inclusion criteria

Women 18 - 65 years old, ≥ 3 documented UTI episodes in the last year, confirmed UTI at entry, informed consent given.

RESULTS

Treatment

Patients received one capsule of OM-89 (Uro-Vaxom®, OM PHARMA) or placebo according to Fig. 1. Treatment of UTI with antibiotics or antiseptics was allowed.

Fig. 1: Treatment schedule (d = days) and control visits

UTI

In OM-89-treated patients, the mean rate of post-baseline UTI was lower than in the placebo group at all visits and the overall cumulative group difference was significant: OM-89: 0.84 vs. Placebo: 1.28, p<0.003 in the intention to treat (ITT) population i.e. 34 % reduction (Fig. 2).

Fig. 2: Cumulative recurrence rate of UTI during the study

The distribution of UTI per patient confirms the preventive effect of OM-89 on UTI recurrences (Fig. 3).

Fig. 3: Distribution of post-baseline UTI per patient

Anti-infective treatment

The mean number of anti-infective prescriptions was significantly lower (p=0.005) in the OM-89 group: 2.44 ± 2.07. In the placebo group: 2.79 ± 2.07.

Symptoms of UTI

The frequency of symptoms of dysuria decreased in OM-89 group as of month 6, but increased in the placebo group at the same visit. A similar pattern was seen for pollakiuria and burning pain (Fig. 4).

Fig. 4: Distribution of symptoms over the study

Safety

No unexpected treatment-related adverse events were reported.

CONCLUSIONS

This 12-month study including 3 months of treatment followed 3 months later by 3 short boosters with OM-89 significantly reduced by 34 % the UTI rate, the need for antibacterial drugs and improved the symptoms.

Tolerance was good and similar to placebo.

These results confirm that OM-89 is a valuable drug for the treatment of recurrent UTIs.

REFERENCE