Uromune – A source of immunity for patients who suffer recurrent urinary tract infections?

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Abstract

To determine the safety and efficacy of MV140 (Uromune) in the prevention of further recurrent urinary tract infections in spinal cord injured patients with recent history of recurrent urinary tract infections.

Introduction

Uromune is an autoimmune agent that is delivered as a sublingual spray. It has been manufactured by INMUNOTEK. It contains a mixture of components of several 'inactivated' bacteria including Escherichia coli, Klebsiella pneumoniae, Enterococcus faecalis and Proteus vulgaris. The composition of Uromune is fixed and there is no variation between doses. Other components in the vaccine are 50% glycerol, pineapple essence, sodium chloride and water.

The intended use of Uromune is for the prevention of recurrent urinary tract infections. It functions to stimulate the innate immune system against common causative organisms of recurrent urinary tract infections as well as alter the adaptive immune response by generating CD4+ T cells against the recognised bacteria within the Uromune, generating immune memory.

A recent study by Lorenzo-Gomez et al. retrospectively assessed the risk reduction of urinary tract infections in 669 women with recurrent UTIs following a three- and six-month course of Uromune[1]. It was reported that there was a 90.28% (95%CI: 87.18-93.38) absolute risk reduction when using Uromune. There was no significant local or systemic side effects in this cohort reported.

Methods and Materials

•We performed a retrospective cohort study on patients who had Uromune therapy with at least 12 months follow up.

•Patients met inclusion criteria if they suffered ≥ 3 urinary tract infections in the prior 12 months prior to the enrolment in the study and had been prescribed Uromune. Urinary tract infections were defined by positive Urine microscopy culture and sensitivity result and patient reported symptoms of urinary tract infection. If patients were already using other forms of UTI prevention strategies, those were continued for the duration of the study.

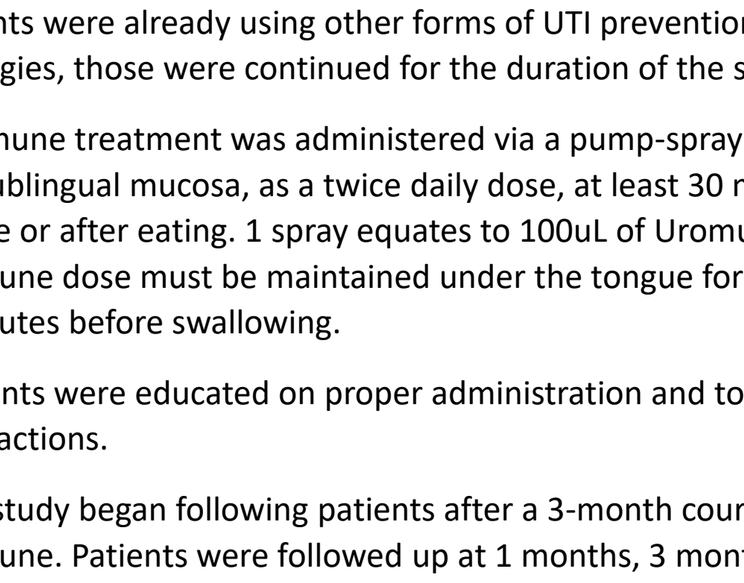
•Uromune treatment was administered via a pump-spray bottle to the sublingual mucosa, as a twice daily dose, at least 30 minutes before or after eating. 1 spray equates to 100uL of Uromune. The Uromune dose must be maintained under the tongue for at least 2 minutes before swallowing.

•Patients were educated on proper administration and to monitor for reactions.

•The study began following patients after a 3-month course of Uromune. Patients were followed up at 1 months, 3 months, 6 months and then 12 months for any adverse events and number of urinary tract infections experienced.

•A significant outcome is defined by a reduction in number of UTI's experienced after Uromune therapy by ≥ 50% in the 12 months post therapy compared with the 12 months prior to therapy.

Table 1: Number of recurrences within 12 months post treatment.



Results

•11 patients (2 female, 9 male) were included in this study. Each with a history of recurrent UTI who received a complete course of the Uromune vaccine and a follow duration of at least 12 months (mean, median time). There was a mean age of 48.5 years, with ages ranging from 31-64.

•Of the 11 patients, 1 patient was on pre-existing microdox therapy which was continued throughout the study period, 3 patients continued taking cranberry supplements and hipprex together.

•The most common organism preceding the treatment was E.coli followed by Klebsiella pneumoniae.

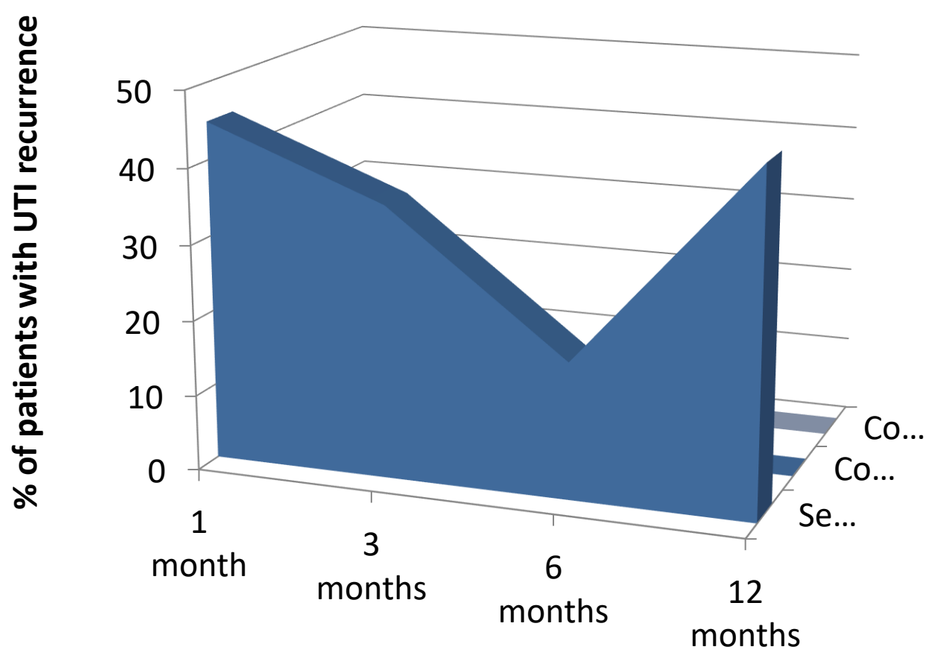
•Within the 12 months follow up period after uromune treatment, 27% (3/11) of patients had 0 UTI's, 27% (3/11) had 1 UTI, 9% (1/11) had 2 UTI's, 9% (1/11) had 7 UTI's, 9% (1/11) had 9 and 9% (1/11) had 12 UTI's. The patient who had 9 UTI's had recurrent pseudomonas infections which isn't targeted by Uromune therapy.

•In the first month, 45% (5/11) patients had had a recurrence of UTI, of which one patient had grown the same organism directly prior to commencement and potentially did not have complete clearance. That patient remained UTI free for another 6 months whilst on Uromune.

•After completion of Uromune therapy, in the first three months only 36% (3/11) patients with UTI's during that period, at 6 months post completion of Uromune therapy only 18% (2/11) patients had UTI's during the follow up period and at 12 months 45% (5/11) patients had UTI's.

•Of the patients who had little to no improvement on Uromune, one patient had recurrent pseudomonas aeruginosa infections and one patient had recurrent infections of Citrobacter koserii, both of which are not targeted by Uromune.

Table 2. Number of patients with recurrences at set time intervals.



Conclusions

Uromune appears to be safe and efficacious is spinal patient with recurrent UTI's. Uromune appears to be most efficacious between 1 months and 6 months where UTI frequency appears to taper off, and by 12 months the frequency appears to increase again. However over the 12 month period, 72% (8/11) patients had less than 3 UTI's in 12 months, of which 63% (7/11) patients achieved the criteria of a 50% reduction in UTI's over the course of the 12 month follow up. No adverse side effects were experienced by any patients. Further longer-term studies will be conducted to assess the optimal timing for repeat dosing to maintain maximal safe efficacy.

References

1. Lorenzo-Gomez M., Padilla-Fernandez B., Garcia-Cenador M., et al. Comparison of sublingual therapeutic vaccina with antibiotics for the prophylaxis of recurrent urinary tract infections. (2015) *Front Cell Infect Microbiol, 5:* p. 50

References

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Click on the border once to highlight and select a different font or font size that suits you. This text is in Arial 16pt and is easily readable up to 6 feet away.