

Novel usage of the Uromune© sublingual vaccine to treat recurrent urinary tract infections in women: Initial experience in the United Kingdom

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Introduction

Recurrent Urinary Tract Infections (UTIs) in women is a prevalent disease and despite treatment, recurrence occurs in up to 60% of patients during the first year. Often these women rely on continuous prophylactic antibiotics.

However multi-resistant bacteria's are emerging, making it prudent therefore to explore prophylaxis that reinforces the natural mechanism of pathogen defence.

We present the **first experience in the United Kingdom (UK)** of the inactivated bacterial vaccine Uromune© in a preliminary cohort of women with recurrent UTIs that have not responded to mainstream treatment including antibiotic prophylaxis.

Methods

Uromune© is currently in the **pre-license Phase III development stage** and is available under the Named Patient Program.

15 women with a mean age 63 yrs (range: 33-86) who suffered with recurrent UTIs (as defined by one proven infection every 3 months), despite lifestyle and medical treatment, received 3 months of Uromune©.

The vaccine is an equal mixture of killed **Escherichia Coli, Klebsiella Penumoniae, Proteus Vulgaris and Enterococcus Faecalis** delivered as a pineapple flavoured sublingual spray.

Prospective observational follow-up was via a nurse specialist phone consultation for 12 months and an on-going direct contact number.

Results

14 out of 15 (87%) women completed the whole course of treatment.

One patient failed to complete the course of treatment due to lifestyle and personal reasons.

12 out of 14 (86%) women who completed treatment reported no subsequent UTIs at 12 month follow up

One patient above remained UTI free for 16 months post vaccine treatment before recurrence. She has now commenced a second course of vaccine.

2 patients suffered recurrence by follow up:

- 1 patient experienced recurrence of her UTI immediately on completion of vaccine
- 1 patient remained UTI free for 5 months from vaccine commencement before her first recurrence

Recurrent UTI



UTI Free

Side Effects

One woman initially discontinued Uromune© due to **severe urosepsis** 9 days into treatment (The patient previously suffered recurrent urosepsis). The patient recommenced and completed Uromune© with no side effects.

One woman initially discontinued Uromune© due to a **concurrent a worsening of her asthma**. The patient recommenced and completed Uromune© with no side effects.

One woman reported **nasal drip** upon commencement of Uromune© - this resolved spontaneously after 1 month and the patient completed Uromune© with no other side effects.

There were no other adverse effects reported.

Conclusions

This small cohort suggest that Uromune© is both **safe and effective** in women with recurrent UTIs who have failed antibiotic prophylaxis.

Further studies are required to evaluate the efficacy of this vaccine in a larger group of patients including a Randomised Control Trial.

A national multi-centre study on the outcomes of Uromune© treatment in the UK is currently being explored with our centre as the lead.

Acknowledgements

Background illustration of E Faecalis from NIH, available at: <https://www.genome.gov/dmd/img.cfm?node=Photos/Microorganisms&id=7909>

