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Lactiale Uro in the prevention of postmenopausal urinary infection: LACMUS study results

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Abstract. Background. The purpose was to assess the efficacy and safety of Lactiale Uro, a product containing two strains of *Lactobacilli* plus cranberry extract and vitamin A, in preventing recurrent urinary tract infections (UTIs) in postmenopausal women (LACMUS study). **Materials and methods.** This was a randomized, prospective, multicenter study. Subjects received Lactiale Uro twice daily for 26 weeks after recovery from UTI; the control group didn't receive the product. The primary endpoint was the proportion of subjects with recurrent UTI episodes at the end of the study. **Results.** Seventy-seven women were screened; 65 were enrolled; 61 completed the study. After 26 weeks, a significantly lower number of women experienced recurrent UTIs with Lactiale Uro compared to no treatment (9.7 vs 23.3 %; $P < 0.05$). Lactiale Uro produced statistically significant improvements, such as lower rates of UTI episodes (12.9 vs 36.6 %; $P < 0.05$); longer time to first UTI episode (136 vs 27 days; $P = 0.0038$); shorter duration of active UTI episode (5 vs 11 days; $P = 0.0199$); and shorter duration of antibacterial therapy for an active UTI episode (4 vs 10 days; $P = 0.0462$). **Conclusions.** Lactiale Uro was safe and effective for the prevention of recurrent UTIs in postmenopausal women. These data require further well-designed trials to clarify possible benefits.

Keywords: *Lactobacilli*; urinary tract infection; postmenopausal period

Introduction

Treatment of recurrent urinary tract infections (UTIs) is an urgent problem. Three most important causes of recurrences in females: anatomical and functional disorders, sexually transmitted infections and postmenopause associated with a number of changes that cause a decrease in resistance to intestinal pathogens [1].

Current guidelines offer a variety of approaches to reduce UTI recurrences, including the use of natural herbal components. However, their use has no certain evidence base. For example, cranberries are considered effective when containing minimum 36 mg of proanthocyanidin (PAC) A (level of evidence: 1b, grade of recommendation: C) [2]; a lower dose is not effective. This was one of the reasons for the exclusion of cranberry products from the guidelines of the European Association of Urology (EAU) in 2014 [3].

However, combined cranberry-containing products are still popular due to their safety and quite convincing efficacy. Our attention was drawn to a study conducted by P. Koradia et al. in premenopausal women with recurrent UTIs, which results were presented in 2019 [4]. This study demonstrated the effectiveness of Bio-Kult Pro-Cyan in the prevention of recurrent UTIs in premenopausal women.

A similar product, Lactiale Uro produced by JSC Farmak, is available on the Ukrainian market. Each capsule contains a concentrate of lactic acid-producing bacteria containing *Lactobacillus acidophilus*, *Lactobacillus plantarum* 5.0×10^8 colony-forming units; cranberry extract containing 18 mg of PAC 254 mg; vitamin A 160 μ g. We designed a study “LACTiale uro in the prevention of postMenopaUSal urinary infection” — LACMUS. The study is an independent test of the efficacy and safety of the product similar to Bio-Kult Pro-Cyan, based on the study conducted by P. Koradia et al. (2019).

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