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P40. EVALUATION OF AN ORAL LACTOBACILLUS PLANTARUM P 17630 MEDICAL DEVICE IN WOMEN WITH RECURRENT VULVOVAGINAL CANDIDIASIS (RVVC): A RANDOMIZED DOUBLE BLIND CONTROLLED CLINICAL STUDY VERSUS PLACEBO.

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Context
Recurrent vulvovaginal candidiasis (RVVC) affects from 5 to 8% women. RVVC is a common problem worldwide and is multifactorial in origin. Many women suffer recurrent episodes that can have serious impact on their quality of life.
Objectives
The aim of the study was to evaluate efficacy and tolerability of an oral Medical Device (MD) containing probiotic Lactobacillus plantarum P 17630 on the vaginal lactobacilli colonization and prevention of elapses.
Methods
We conducted a randomized double-blind placebo controlled study approved by Ethical Committee. The schedule treatment consisted of 3 cycles of 15 days intake and 15 days washout. The entire duration of the study was 90 days.
Patients
93 women aged between 18-58 years with clinical history of recurrent yeast vaginitis (>3 relapses within 1 year) were included. Participants reported clinical symptoms of yeast or associated bacterial vaginosis or laboratory confirmed bacterial infections. Participants under antimicrobial drugs treatment for vaginal infections or chronic antibiotic or corticosteroid treatment were excluded.
Intervention
The oral capsules contained 5x10E9CFU/capsule of L. plantarum P 17630, patented by Proge Farm Srl (Novara, Italy), or placebo and were administered randomly to women with RVVC.
Main Outcome Measures
The primary endpoint of the study was the evaluation of the vaginal colonization with lactobacilli using the lactobacillary grading (LBG) score. The secondary endpoint was the assessment of the vulvovaginal conditions and signs and the tolerability of the product.
Results
A total number of 93 participants received the treatment. Oral MD significantly improved clinical outcomes. The results demonstrated a statistical significant difference in LBG score when comparing D0 to D45 ($p<0.001$) and D0 to D90 ($p=0.001$). The improvement in LBG score was significantly higher in

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participants who received L. plantarum P 17630 MD compared to placebo ($p<0.005$). Also, based on the physician assessment, the improvements of the clinical symptoms was observed in oral MD treatment group. Oral MD treatment was well tolerated, no side effect was recorded during the study.
Conclusions
This study suggests that oral probiotic Lactobacillus plantarum P17630 MD improves vagina colonization of acid lactic bacteria confirmed by the amelioration of vaginal LBG score. The normalisation of the vagina microbiota prevent new episodes of vulvovaginal candidiasis. The oral MD was well tolerated.