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P98. USE OF A CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN PATIENTS WITH PRECANCEROUS HPV LESIONS. INTERIM ANALYSIS RESULTS

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Context: PapilocareÂ® is a non-hormonal Coriolus versicolor-based vaginal gel. In patients with HPV infection, a regression effect of the LSIL in cervix and a significant virus clearance have been observed after 1-year administration of oral Coriolus versicolor.
Objective: To evaluate the efficacy of PapilocareÂ® to repair cervical mucosa in women with HPV-related pap alterations and consistent colposcopy image.
Methods: Randomized, open-label, parallel-group, controlled clinical trial.
Patients: Currently recruiting 96 positive-HPV women age 30 to 65 with pap result of ASC-US, LSIL or AG-US and concordant colposcopy image.
Interventions: Patients are randomized into 3 groups: A) PapilocareÂ® 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months; B) PapilocareÂ® 1 cannula/day for 3 months + 1 cannula/alternate days for 3 months; C) no treatment as usual practice.
Main outcome measures: Interim analysis of secondary endpoints - changes in epithelialization of the cervix evaluated by standard colposcopy and in perceived stress evaluated by PSS14 - are presented. PapilocareÂ® arms (A+B) were combined for this evaluation.
Results: Data from 47 patients at 3 months and 29 at 6 months are available. 20.7% and 47.5% of patients in PapilocareÂ® group vs 22.2% and 16.7% in control group improved the cervix epithelialization at month 3 and 6 respectively (p=ns). At month 3, a trend to stress reduction vs basal was observed in the treatment group (-0.9 points) and was significant at month 6 (-2.9; p=0.045, StudentÂ´s t-test). Patients in control group showed a trend to stress increase (+0.5 and +4.7; p=ns) at month 3 and 6, respectively. There were not significant differences between treatment groups.
Conclusion: In these interim analysis results, PapilocareÂ® shows a positive trend in cervix epithelialization and a significant stress reduction; these findings need to be confirmed upon study completion.

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