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P96. EFFICACY OF A CORIOLUS VERSICOLOR-BASED VAGINAL GEL TO REPAIR CERVICAL MUCOSA WITH HIGH-RISK 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: Preliminary analysis of primary endpoint (% of patients with normal pap and concordant colposcopy image) at 3 and 6 months and the secondary endpoint (% of patients with HPV cleared) at 6 months in the subgroup of patients with high-risk HPV are presented. PapilocareÂ® arms (A+B) were combined for this evaluation.
Results: Data from 28 patients at 3 months and 18 at 6 months are available. At 3 months, 67% of patients using PapilocareÂ® (n=18) normalized pap and colposcopy vs. 20% in control group (n=10) (p=0.046; Fisher test). At 6 months, 73% (n=11) vs 33% (n=6) of patients repaired cervical lesions in PapilocareÂ® and control groups, respectively (p=ns). HPV clearance at 6 months was observed in 50% of high-risk patients in PapilocareÂ® group vs 17% in control group (p=ns)
Conclusion: In these interim analysis results, PapilocareÂ® shows a significant difference in repairing HPV-cervical lesions at 3 months versus control and a positive trend in both HPV clearance and HPV-cervical lesions repairing at 6 months; these findings need to be confirmed upon study completion.

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