6th Annual Congress on
Gynecology and Women's Health
November 21, 2022 | Webinar

Received date : 30-10-2022 | Accepted date : 02-11-2022 | Published dare : 05-12-2022

Efficacy of a Multi-ingredient Coriolus versicolor-Based Vaginal Gel in High-Risk HPV Women Over 40 : Sub-analysis of the Paloma Clinical Trial & Papilobs Real-Life Study

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Background/Objectives: HPV clearance and resolution of cervical HPV-dependent lesions become difficult in peri and postmenopausal women. The objective of this analysis was to evaluate the effect of the Papilocare®, a multi-ingredient Coriolus versicolor-based vaginal gel in repairing the High-Risk (HR) HPV-dependent low-grade cervical lesions in women over 40 years.

Methods: Paloma study1,2 (ClinicalTrials.gov NCT04002154) was a multicenter, randomized, open-label, parallel-group, watchful waiting approach-controlled clinical trial. Unvaccinated HPV positive women aged between 30-65 with cytology of ASCUS or LSIL and concordant colposcopy image were randomized into 3 groups:

A) Papilocare® 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months;

B) Papilocare® 1 cannula/day for 3 months + 1 cannula/alternate days for 3 months;

C) Control group: watchful waiting approach. Papilobs study3 (ClinicalTrial.gov: NCT04199260) was an observational, multicenter, prospective, one-cohort study. Vaccinated or not HPV-positive women aged > 25y with vivo cytology of ASCUS or LSIL and concordant colposcopy were included. Patients were treated with Papilocare® 1 cannula/day for 21 days during first month + 1 cannula/alternate days for 5 months. Percentages of patients with normal cytology and concordant colposcopy after 6 months of treatment in the HR-HPV population are presented.

Results: A total of 30 and 68 HR-HPV patients above 40yo were evaluated in Paloma and Papilobs studies, respectively. In the Paloma trial, normal cytology and concordant colposcopy was observed in 90% vs 33% patients in A+B Papilocare® and control groups, respectively, (p=0.003, Fisher test). In the Papilobs study, normal cytology and concordant colposcopy was achieved in 73,5% of patients.

Conclusions: After a 6-month treatment period, Papilocare® showed a clinically robust and statistically significant efficacy in repairing cervical HR-HPV lesions in women over 40 years vs watchful waiting approach. This efficacy was corroborated in the real-life study in more than 2/3 of the HR-HPV patients above 40.

Recent Publications

1. Serrano, Luis et al. “Efficacy of a Coriolus versicolor-Based Vaginal Gel in Women With Human Papillomavirus-Dependent Cervical Lesions: The PALOMA Study.” Journal of lower genital tract disease vol. 25,2 (2021): 130-136.
2. González, Silvia, et al. “Effect of a Coriolus versicolor-based vaginal gel on cervical epithelialization and vaginal microbiota in HPV-positive women: EPICERVIX pilot study”. Academic Journal of Health Science. 2022/37 (2): 139-145.
3. Criscuolo, Anna Angela et al. “Therapeutic Efficacy of a Coriolus versicolor-Based Vaginal Gel in Women with Cervical Uterine High-Risk HPV Infection: A Retrospective Observational Study.” Advances in therapy vol. 38,2 (2021): 1202-1211.