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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 study^{1,2} (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 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.

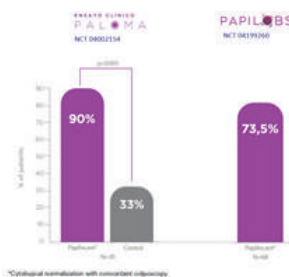


Figure: Low-degree cervical lesions repairing at 6 months in high-risk HPV women > 40 years

Biography

Yann Gaslain, CEO of Procure Health pharmaceutical company, is one of the ten entrepreneurs to achieve the deserved international distinction "10 Most Successful Entrepreneurs Revamping the Pharmaceutical Industry Worldwide" of 2021. Currently, Procure Health laboratory is extended its branches in France, Portugal, and distributes its products in more than 60 countries around the world.

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