Abstract Presentado en:
36th International Papillomavirus Conference & Basic, Clinical and Public Health Scientific Workshop (IPVC 2024)
X European Federation of Colposcopy (EFC) Congress 2024

EFFICACY OF A MULTI-INGREDIENT *CORIOLUS VERSICOLOR*-BASED VAGINAL GEL ON HIGH-RISK HPV CLEARANCE: PRELIMINARY RESULTS FROM THE PALOMA 2 CLINICAL TRIAL

Cristina Centeno[1], Mario Coll[2], Gabriel Fiol[3], Belén López Cavanillas[4], Margarita Riera[5], Orlando Valenzuela[6];
[1]Hospital Universitari de la Vall d'Hebron, Barcelona, Spain, [2]Hospital Universitario Son Espases, Palma De Mallorca, Spain, [3]Clínica Alborán, Almería, Spain, [4]Hospital Universitario La Paz, Madrid, Spain, [5]ASSIR CAP Torrassa, Hospitalet De Llobregat, Spain, [6]Ancla Clínica Ginecológica, Vigo, Spain

Introduction

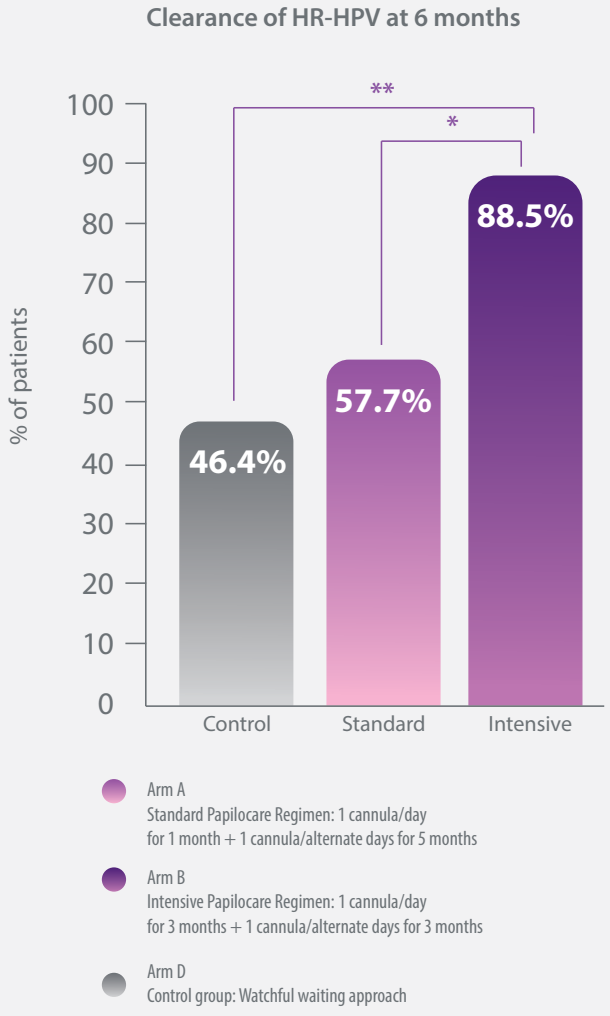
HR-HPV infection is a critical precursor to cervical cancer. The PALOMA 2 clinical trial was designed to assess the efficacy of a *Coriolus versicolor*-based vaginal gel, Papilocare®, in facilitating HR-HPV clearance as one of the secondary endpoints.

Methods

Randomized, multi-centre, prospective, open-label, parallel-group, watchful waiting approach-controlled clinical trial. Unvaccinated HR-HPV positive women between 30-65-year-old, with ASCUS/LSIL cytology and concordant colposcopy were randomized into 3 groups: A) Standard Papilocare® regimen: 1 cannula/day for 1 month + 1 cannula/alternate days for 5 months; B) Intensive Papilocare® regimen: 1 cannula/day for 3 months + 1 cannula/alternate days for 3 months; C) Control group: watchful waiting approach. Preliminary results of arm A, B vs D on HR-HPV clearance after 6 months of treatment are presented. The study assessed HR-HPV clearance after six months, categorized as complete (negative HR-HPV test or no detectable baseline genotypes) or partial (disappearance of at least one genotype with normal cytology and concordant colposcopy). Ethical approval was obtained, and all participants gave informed consent.

Results

A total of 116 patients with a mean age of 40.5 years were randomized. The 48.5% were smokers without differences between groups. From the 80 patients (A= 26; B= 26; D= 28) who completed the 6-month treatment, 57.7% (A), 88.5% (B) vs 46.4% (D) obtained HR-HPV clearance (pAvsD=0.4078, pBvsD=0.0011.



Conclusions

Preliminary findings indicate that the Papilocare® gel, particularly in the intensive regimen (B), significantly enhances HR-HPV clearance compared to watchful waiting approach. These results support the potential of Papilocare® as a proactive management option for women with HPV-dependent low-grade cervical lesions. Final analysis will further clarify these impacts.