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EFFICACY OF INTENSIVE REGIMEN OF A MULTI-INGREDIENT *CORIOLUS VERSICOLOR*-BASED VAGINAL GEL IN HR-HPV CLEARANCE: PRELIMINARY POOLED RESULTS FROM THE PALOMA 1 AND PALOMA 2 CTS

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Introduction

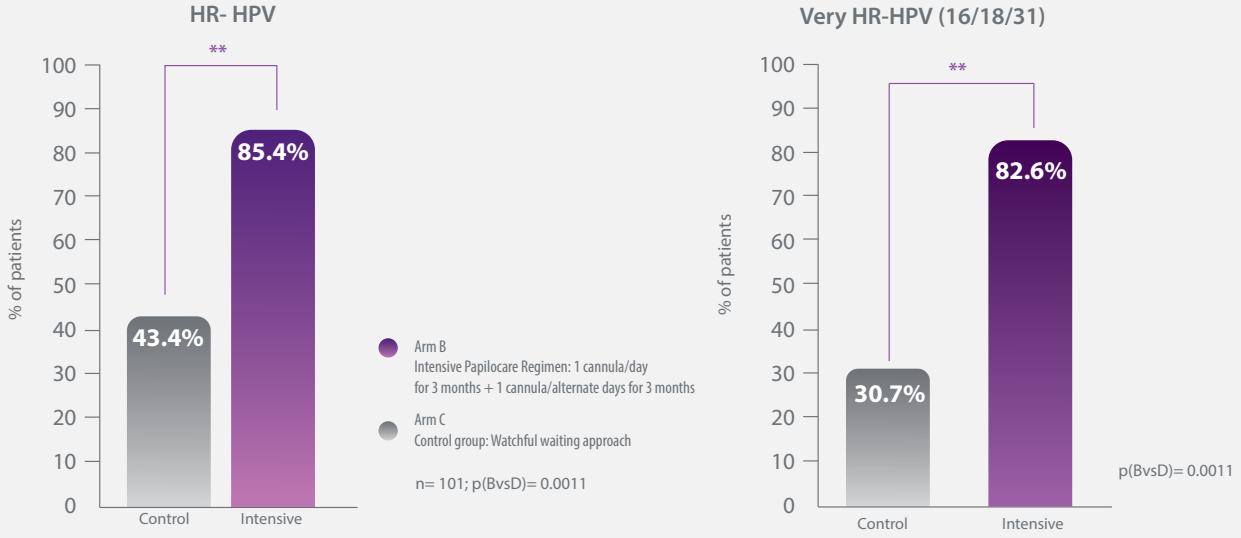
PALOMA 11 was the inaugural clinical trial (CT) demonstrating the efficacy of a *Coriolus versicolor*-based vaginal gel (Papilocare®) in repairing low-grade cervical lesions related to HPV. Building on this, PALOMA 2 exclusively focused on a high-risk (HR)-HPV positive cohort, aiming to assess the efficacy of intensive regimen of Papilocare® in promoting HR-HPV clearance.

Methods

Randomized, multicentre, prospective, open-label, parallel-group, watchful waiting approach-controlled CTs. Unvaccinated HR-HPV positive women aged between 30-65 with ASCUS/LSIL cytology and concordant colposcopy were randomized into 3 groups: Standard Papilocare® posology: 1 cannula/day for 1 month+1 cannula/alternate days for 5 months; Intensive Papilocare® posology: 1 cannula/day for 3 months+1 cannula/alternate days for 3 months; Control group: watchful waiting approach. This analysis presents pooled preliminary results focusing on HR-HPV (secondary endpoint) clearance at six months for the intensive regimen versus control. HPV clearance was considered as total (negative HPV test or disappearance of all species detected at baseline) or partial (disappearance of at least 1 HPV genotype present at baseline visit, together with normal cytology and concordant colposcopy observations). All patients signed informed consent, and studies were approved by centralized IRBs.

Results

Data from 101 patients has been evaluated, 48 from Papilocare® group (22, PALOMA 1; 26, PALOMA 2) and 53 patients from the control group (25, PALOMA 1; 28, PALOMA 2). Significant increase of HR-HPV clearance was shown in Papilocare® group vs control group (85.4% vs 43.4%, p< 0.0011). The very HR sub-group (patients with 16 and/or 18 and/or 31 genotype at baseline) showed similar results: 82.6% vs 37.0.% (p< 0.0011) for Papilocare® and control group, respectively.



Conclusions

While awaiting final results from PALOMA 2, these preliminary findings suggest that the intensive regimen of Papilocare® significantly enhances HR-HPV clearance, affirming its potential as a valuable clinical tool for managing HR-HPV infections compared to watchful waiting approach.

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