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EFFICACY OF INTENSIVE REGIMEN OF A MULTI-INGREDIENT *CORIOLUS VERSICOLOR*-BASED VAGINAL GEL IN INCREASING HPV CLEARANCE: RESULTS FROM THE PALOMA CLINICAL TRIAL

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Introduction

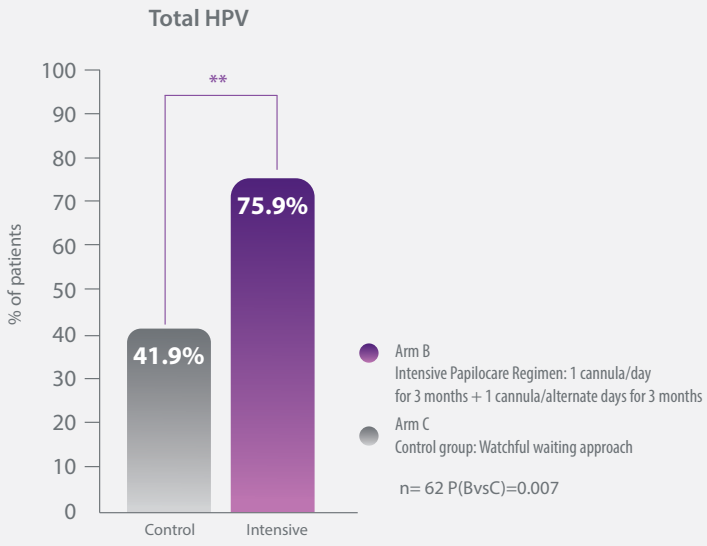
Cervical cancer is intimately linked to HPV persistency. Although most of HPV infection will clear out spontaneously within two years, many factors increase the persistency risk, such as viral genotype. In the PALOMA clinical trial one of the reported secondary outputs was the efficacy of a *Coriolus versicolor*-based vaginal gel (Papilocare®) increasing viral clearance.

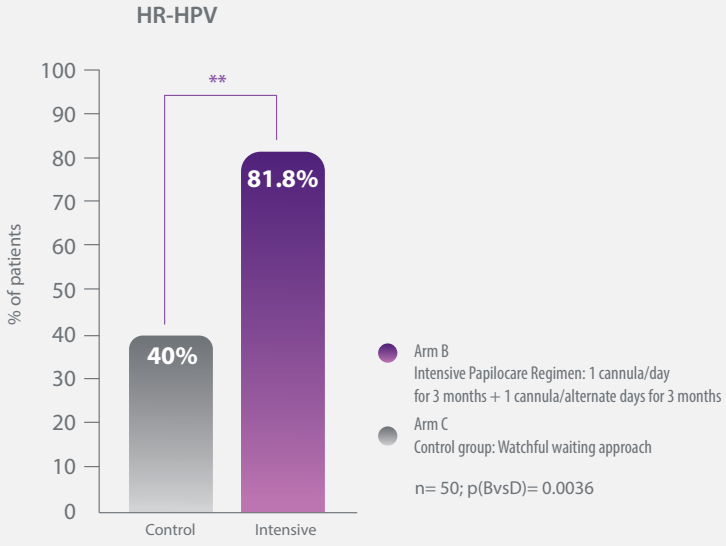
Methods

Randomized, multi-center, open-label, parallel-group, watchful waiting approach-controlled clinical trial. Unvaccinated HPV-positive women aged between 30-65 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. Results of arm B vs C on HPV clearance are presented. HPV clearance was considered as total clearance (negative HPV test or the disappearance of all species detected at baseline) or partial clearance (disappearance of at least 1 HPV genotype present at the baseline visit, together with normal cytology and concordant colposcopy observations).

Results

91 HPV-positive women were included in the study. The mean age of the patients was 40.5 years. From the 31 HPV-positive women in the B arm, 24 were high-risk (HR)-HPV positive, whereas, in the control group, 26 out of 31 women were HR-HPV positive. The intensive regimen showed significant increase of HPV clearance compared with the control group, both in total HPV (75.9% vs. 41.9%, p=0.007) and HR-HPV positive (81.8% vs. 40.0%, p=0.0036) population.





Conclusions

After a 6 month-treatment period, an intensive regimen of Papilocare® significantly increased HPV clearance in patients infected with HR-HPV genotypes compared to conventional watchful waiting approach. These findings underscore the potential of Papilocare® as an effective intervention in promoting HPV clearance and reducing cervical cancer risk.