Effect of a multi-ingredient vaginal gel in HPV infected women: normalizing HPV-dependent cervical lesions (ASCUS/LSIL) and high-risk HPV clearance

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Background/Objective:

In previous clinical studies Papilocare®, a non-hormonal multi-ingredient vaginal gel, has shown to significantly influence the re-epithelialization of the cervix and the rebalancing of the vaginal microbiota that favors the natural process of vaginal immunity.

The objective of this study was to evaluate the effect of Papilocare® on the normalization of cervical HPV-dependent atypia (ASCUS and LSIL) and associated colposcopic alterations, and on the clearance of high-risk HPV (HR-HPV).

Methods

Multicenter, randomized, open-label, parallel-group, usual practice-controlled clinical trial (Paloma Clinical Trial).

Unvaccinated HPV+ women aged between 30 and 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: no treatment (usual clinical practice)

Percentage of patients with normalization of the lesions (normal cytology and concordant colposcopy image) as the primary endpoint and percentage of patients with HR-HPV clearance (total clearance or baseline-HPV partial clearance together with cytological and colposcopy normalization) were evaluated at 6 months.

Pap smear evaluation and HPV identification (Clart® HPV4) were blind and centrally-conducted by an independent researcher at the IECM laboratory (Lugo, Spain). Papilocare® arms (A+B) were combined as treatment group and Chi-square test was used.

Conclusions

After the six-month treatment period, Papilocare® has shown statistically significant efficacy in normalizing HPV-dependent cervical lesions (cytology of ASCUS/LSIL and concordant colposcopy images), especially in HR-HPV subpopulation. A trend to increase HPV clearance has also been observed in HR-HPV subpopulation.

Results

A total of 84 patients (mean age of 41 yo, evenly distributed among groups; total population) were evaluated (53 vs 31 in treatment and control groups, respectively) of which 66 were HR-HPV (HR-HPV subpopulation; 41 vs 25 in treatment and control groups, respectively). Results of patients with cytology normalization and concordant colposcopy at 6 months in both total and HR-HPV populations are shown in **Figure 1**.

Figure 2 shows clearance results in HR-HPV subpopulation at 6 months.

Normalized cytology with concordant colposcopy at 6 months (Primary Endpoint)

Figure 1: Papilocare® on repairing cervical lesions (ASCUS/LSIL cytology and concordant colposcopy image)

High-risk HPV clearance at 6 months (Secondary Endpoint)

*HR-HPV: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68

Figure 2: Papilocare® on high-risk HPV clearance.