626 EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV INFECTED PATIENTS: RESULTS OF 7 DIFFERENT STUDIES

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Introduction/Background* To evaluate the consistency of the efficacy of a multi-ingredient Coriolus versicolor-based vaginal gel, Papilocare®, on high-risk HPV (HR-HPV) clearance in 7 different studies.

Methodology Results of the 6 month-treatment period of Papilocare ® from 5 independent observational (3 Spanish and 2 Italian hospitals) were compared to results from a randomized, open, parallel, controlled trial (Paloma: ClinicalTrials.gov NCT04002154) and an observational, multicenter, prospective, one-cohort study (PapilOBS: ClinicalTrial.gov NCT04199260). Two prospective one-cohort (Vigo and Bari), 2 retrospective one-cohort (Coruña and Hospitalet) and 1 retrospective controlled (Roma) studies have been performed.

Vigo study. Secondary endpoint (SE): HPV clearance in 25 patients infected by HPV 16 and/or 18.

Bari study. Primary endpoint (PE): HPV clearance in 98 HR-HPV patients.

Coruña study: PE; HPV clearance assessed in 57 medical patients' records.

Hospitalet study. PE: composite efficacy variable (patients with normal cytology and/or HPV clearance) in 91 HR-HPV patients.

Roma study. PE: HPV clearance in 183 HR-HPV patients.

PapilOBS study. SE: HR-HPV clearance in 178 patients.

Paloma trial. SE: HR-HPV clearance in 66 patients.

Result(s)* After the 6-month treatment period, 48% and 57% of patients cleared HPV 16-18 and HR-HPV in Vigo and Bari studies, respectively. 58% of reduction was observed in the number of HR-HPV patients (Coruña) and 72.5% of patients negativized cytology and/or cleared HR-HPV (Hospitalet). 67% HR-HPV clearance was observed (treated group) vs 37.2% (control group), p<0,0001 in the Roma study. In the Paloma trial, HR-HPV clearance reached 63% (treated group) vs 40% (control group). Similar rate of 57.4% HR-HPV clearance was observed in the PapilOBS study.

Conclusion* Papilocare® has shown clinically significant consistent rates of HR-HPV clearance ranging from 50% to 70% in 7 different studies and 827 patients. These results reinforce the evidence of its beneficial effect for HR-HPV patients.

641 EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HPV+ WOMEN OVER 40 YEARS OLD : A SUB-ANALYSIS OF THE PALOMA CLINICAL TRIAL

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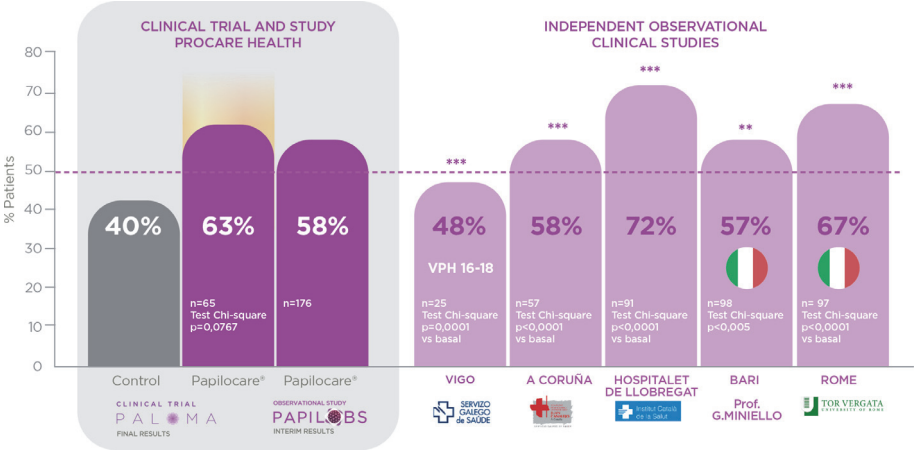
Introduction/Background* HPV clearance and resolution of cervical HPV-dependent lesions become difficult in peri and postmenopausal women. The objective of this sub-analysis was to evaluate the effect of the Papilocare®, a multi-ingredient Coriolus versicolor-based vaginal gel in repairing the HPV-dependent low-grade cervical lesions in women over 40 years.

Methodology

Paloma study (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 (usual clinical practice). Primary endpoint:% of patients with normal cytology and concordant colposcopy after 6 months of treatment in the total population, high-risk (HR) HPV (16,18,31,33,35,39,45,51,52,56,58,59,68) and very HR HPV (patients infected by any combination of 16, 18 and 31) subpopulations. Pap smear evaluations were blind and centrally conducted by an independent researcher at the IECM laboratory (Lugo, Spain). Papilocare® arms (A+B) were combined as treatment group.



Abstract 626 Figure 1

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Result(s)* A total of 38 out of 84 evaluable patients at 6 months included in Paloma trial were above 40yo [mean(SD) age: 47.71(5.56)], of which 30 and 13 were HR HPV and 16-18-31 HPV patients, respectively. At 6 months, normal cytology and concordant colposcopy was observed in 92%, 90% and 75% of patients treated with Papilocare® vs 50%, 33% and 40% of patients in control group, in the total, HR and 16-18-31 populations (p=0.0066; p=0.0031; p=0.2929, Fisher test) respectively.
Conclusion* Papilocare® showed a robust and clinically significant efficacy in repairing cervical HPV lesions in women over 40 years, with a statistically significant difference vs control group in the total and HR populations.

648 TUBECTOMY WITH DELAYED OOPHORECTOMY AS ALTERNATIVE FOR RISK-REDUCING SALPINGO-OOPHORECTOMY IN HIGH-RISK WOMEN TO ASSESS THE SAFETY OF PREVENTION

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Introduction/Background* Risk-reducing salpingectomy (RRS) with delayed oophorectomy (DO) has gained interest for women at high risk for ovarian cancer in the last years. In the first place because of the increasing number of studies pointing towards the fallopian tube as tissue of origin. In the second place because two studies demonstrated the positive effect on menopause-related quality of life and sexual functioning compared to standard risk reducing salpingo-oophorectomy (RRSO). However, the strategy is not yet proven to be safe. In the current TUBA-WISP II study, we aim to investigate whether RRS with DO is non-inferior to the current standard RRSO regarding ovarian cancer risk.
Methodology In this international prospective multicenter preference trial, women choose between the novel RRS with DO and the current standard RRSO. RRS can be performed after the completion of child bearing and until the age of 40 (*BRCA1*), 45 (*BRCA2*) or 50 (*BRIP1, RAD51C and RAD51D* pathogenic variant (PV) carriers). Subsequent DO is recommended at a maximum delay of five years beyond the upper limit of the current guideline age for RRSO. The current guideline age, which is also recommended for RRSO within the study, is 35-40 for *BRCA1*, 40-45 for *BRCA2* and 45-50 for *BRIP1*, *RAD51C*, and *RAD51D* PV-carriers. The primary outcome measure is the cumulative ovarian cancer incidence at target age: 46 for *BRCA1* and 51 for *BRCA2*-PV carriers. A total 1500 *BRCA1* and 1500 *BRCA2-PV* carriers are needed to prove non-inferiority of RRS with DO compared to RRSO. Kaplan-Meier analysis with Inverse probability weighting will be used to estimate the cumulative incidence at the appropriate target age (46 or 51) per *BRCA*-type.
Result(s)*
Conclusion* As RRS with DO is proven to be beneficial in regard to menopause-related quality of life and sexual functioning, the current international study is investigating the non-inferiority to RRSO regarding ovarian cancer incidence.
Trial registration NCT04294927

698 REAL-LIFE EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV PATIENTS: THE PAPILOBS STUDY FINAL RESULTS

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Introduction/Background* The objective was to evaluate the efficacy of Papilocare® -a multi-ingredient Coriolus versicolor-based vaginal gel- on repairing high-risk (HR) HPV-dependent low-degree cervical lesions and HR-HPV clearance in real-life practice.
Methodology Observational, multicenter, prospective, one-cohort study (PAPILOBS study ClinicalTrial.gov: NCT04199260). Vaccinated or not HPV-positive women aged > 25y with Pap smear (Ps) of ASCUS or LSIL and concordant colposcopy were included during routine clinical visits in Spain. Patients were treated with Papilocare® 1 cannula/day for 21 days during first month + 1 cannula/alternate days for 5 months. After this 6-month period, patients with altered cytology and/or HPV persistency were treated for a 6-month extension treatment period with the same dosage. Analysis of HR-HPV patients with normal Ps and concordant colposcopy image (primary endpoint) and patients with HR-HPV cleared (totally or partially together with negative Ps and normal colposcopy) at 6/12 months is presented. The study was approved by an IRB and informed consent was signed by patients.
Result(s)* At 6 months, data of 178 and 176 patients for Ps/colposcopy and HR-HPV presence, respectively, were available. 68% of patients (121/178) had negative Ps and concordant colposcopy. HR-HPV clearance was observed in 57.4% of patients (101/176). Data of 68 patients included in the 6-month extension treatment period for Ps/colposcopy and HR-HPV presence were available. At 12 months, 79.4% (54/68) of patients had negative Ps and concordant colposcopy and HR-HPV clearance was observed in 61.7% (42/68). Considering all study period, 76.4% and 70.6% of patients repaired HR-HPV-dependent cervical lesions and cleared HR-HPV, respectively.
Conclusion* In this real-life study, repairing of HR-HPV-dependent low-degree cervical lesions and clearing HR-HPV were achieved after 6-month treatment with Papilocare® (extending it up to 12-months if needed) in 3 out of 4 patients. These findings are consistent with the Paloma Trial's' ones (ClinicalTrials.gov NCT04002154) and other observational studies results.

743 FEASIBILITY AND THE EFFICACY OF RRSO COMBINED WITH SIMULTANEOUS MASTECTOMY AND BREAST RECONSTRUCTION IN BRCA 1–2 PATIENTS

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