



# EFFECTIVENESS OF A MULTI-INGREDIENT *CORIOLUS VERSICOLOR*-BASED VAGINAL GEL IN HIGH-RISK HPV PATIENTS IN OVER 35- OR 40-YEAR OLD SUBGROUPS

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## INTRODUCTION

HR-HPV persistence is a prerequisite for cervical cancer development, which is the fourth most common cancer in women. The aim of this study is to evaluate the effectiveness of a *Coriolus versicolor*-based vaginal gel- on repairing high-risk (HR) HPV-dependent low-degree cervical lesions and HR-HPV clearance in real-life practice.

## METHODS:

Observational, multicenter, prospective, one-cohort study (NCT04199260) recruited a total population of 178 woman over >25y with an ASCUS/LSIL Pap smear and concordant colposcopy during routine clinical visits. Patients have been treated with *Coriolus versicolor*-based vaginal gel 1 cannula/day for 21 days the first month+ 1 cannula/alternate days for 5 months. Sub-analysis of women over 35 and/or 40 years old infected with HR-HPV, data from colposcopy and concordant Pap smear results (primary endpoint) and viral clearance at 6/12 months are presented. The study was approved by the ethical committee of Public University Hospital of Puerta de Hierro (Madrid). All patients signed informed consent.

## RESULTS:

Data collected from women  $\leq 35$  or  $\leq 40$  years old shown 64% and 64.5% (at 6 months), and 74.7% and 72.7%(at 12 months) Pap smear/colposcopy normalization and concordant colposcopy respectively, whilst viral clearance was 55.4% and 56% (at 6 months), and 67.6% and 68.8% (at 12 months) respectively.

Additionally, data collected from women  $\geq 35$  or  $\geq 40$  years old shown 70.9% and 73.5% (at 6 months), and 76.9% and 81.2% (at 12 months) Pap smear/colposcopy normalization and concordant colposcopy respectively, whilst viral clearance was 58.8% and 59.7% (at 6 months), and 72.8% and 73.5% (at 12 months) respectively.

## CONCLUSIONS:

In this subpopulation analysis of HR-HPV low-degree cervical lesions normalization and clearance, women aged  $\geq 40$  years old showed similar or better ratios than the  $\leq 40$  years old group at the two studied timepoints pointing to the effectiveness of *Coriolus versicolor*-based vaginal gel even in that more vulnerable patients group to HR-HPV persistency.